UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01- 12257-PBS** **Subcategory Case. No. 06-11337**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Judge Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

DEY, INC., DEY, L.P., AND DEY L.P., INC.'S INDIVIDUAL LOCAL RULE 56.1 STATEMENT IN OPPOSITION TO THE UNITED STATES' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO DEY

Pursuant to Local Rule 56.1, Defendants Dey, Inc., Dey, L.P., and Dey L.P., Inc. (collectively, "Dey") submit the following opposition to the United States' Local Rule 56.1 Statement of Undisputed Material Facts as to Dey (the "US-SOF").

I. GENERAL RESPONSES AND OBJECTIONS

Dey generally objects to the US-SOF on the grounds that the unnumbered headings misstate, misconstrue and/or mischaracterize the underlying alleged "undisputed" facts they purport to introduce. Dey further objects to the US-SOF in that these unnumbered headings lack adequate foundation. *See* Fed. R. Evid. 602. Accordingly, Dey omits these improper and argumentative headings in its Specific Responses to the US-SOF below. In addition, Dey generally objects to the US-SOF insofar as it inappropriately conjoins completely unrelated or marginally related statements together as one purported factual statement. Dey generally objects to the US-SOF insofar as it does not specifically relate to the Dey drugs at issue on this motion. Dey generally objects to the US-SOF insofar as it is immaterial to the issues before the Court on

the present motion. Dey generally objects to the citation of evidence which does not support a particular fact or is not the best evidence of a particular fact. Dey's agreement that a fact is undisputed is not an agreement that Plaintiffs' citations support such fact.

II. SPECIFIC RESPONSES TO PLAINTIFFS' STATEMENT OF ALLEGED FACTS

1. The Plaintiffs hereby incorporate by reference the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants, filed this date.

Dey's Response: Dey hereby incorporates by reference Defendants Abbott Laboratories, Inc., Dey, Inc., Dey, L.P., Dey L.P., Inc., and Boehringer Ingelheim Roxane, Inc.'s Combined Response to the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants.

2. Defendant Dey, Inc. is a corporation organized under the laws of Delaware with its principal offices in Napa, California. Prior to June 30, 1998, Dey, Inc. was known as "Dey Laboratories, Inc." (United States' First Amended Complaint (hereinafter "Complaint") ¶ 12; Dey, Inc., Dey L.P., Inc., and Dey, L.P.'s Answer and Defenses to the United States' First Amended Complaint (hereinafter "Answer") ¶ 12.)

Dey's Response: Dey does not dispute US-SOF No. 2.

3. Dey, Inc. is the general partner of the defendant Dey L.P., a limited partnership, and is the sole owner of the other partner, defendant Dey L.P., Inc. (Complaint ¶¶ 13-14; Answer ¶¶ 13-14.) The three Dey entities are collectively referred to herein as "Dey."

Dey's Response: Dey does not dispute US-SOF No. 3.

4. In approximately 1990 Dey was acquired by Lipha Pharmaceuticals. In approximately January 2001, Lipha changed its name to EMD, Inc. Dey is wholly owned by EMD, Inc. Effective October 2, 2007, EMD, Inc., including Dey, was acquired by Merk S.A., which in turn is wholly owned by Merk KGaA. (Declaration of George B. Henderson, 11 ("Henderson") Ex. 1, at 20-21)

Dey's Response: Dey disputes US-SOF No. 4. Lipha Pharmaceuticals, Inc., a subsidiary of Lipha Chemicals, Inc. acquired Dey in 1988. Lipha Pharmaceuticals, Inc. changed its name to Dey Laboratories, Inc. in 1988. On January 1, 1990, Lipha Chemicals, Inc. transferred its ownership interest in Dey to EMD, Inc. Lipha Chemicals, Inc. then changed its

name to Lipha Pharmaceuticals, Inc. In 1991, Merck KGaA acquired a majority interest in Merck S.A. At that time, Merck S.A. owned one hundred percent (100%) of the shares of EMD, Inc. EMD, Inc. has owned one hundred percent (100%) of the shares of Dey, Inc.

5. On or about October 2, 2007, Dey was acquired by Mylan Pharmaceuticals, Inc. (Henderson Ex. 2, at 38-41)

Dey's Response: Dey disputes US-SOF No. 5. Ninety-nine percent (99%) of the limited partnership interest in Dey, L.P. is owned by Dey Limited Partner, Inc.; one percent (1%) of the limited partnership interest in Dey, L.P. is owned by Dey, Inc.; one hundred percent (100%) of the shares of Dey Limited Partner, Inc. are owned by Dey, Inc.; one hundred percent (100%) of the shares of Dey, Inc. are owned by EMD, Inc.; one hundred percent (100%) of the shares of EMD, Inc. are owned by Mylan Delaware Inc.; one hundred percent (100%) of the shares of Mylan Delaware Inc. are owned by Mylan Pharmaceuticals Inc.

6. Dey's five-digit labeler code is 49502. Dey has sold Albuterol, Albuterol Sulfate, Cromolyn Sodium, and Ipratropium Bromide in various package sizes and strengths. (Complaint ¶ 29; Answer ¶ 29.)

Dey's Response: Dey does not dispute that its five-digit labeler code is 49502. Dey does not dispute that it has sold albuterol sulfate, cromolyn sodium, and ipratropium bromide in various package sizes and strengths, but refers to and incorporates herein by reference Paragraph No. 46 of the Dey Defendants' Statement of Undisputed Material Facts In Support of Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion for Partial Summary Judgment, Docket 6190, (the "Dey-SOF") for the specific formulations, strengths, package sizes, NDCs, and first and last shipment dates of these drugs that Dey has sold.

7. In 1991, Dey signed a Medicaid Rebate Agreement with the Secretary of Health and Human Services. (Declaration of Sarah L. Reid In Support of Dey L.P, Dey L.P., Inc., and Dey L.P. Inc.'s Motion For Partial Summary Judgment ("Reid Decl."), Ex. 34.) An accompanying letter to Dey informed Dey that under the Medicaid program States receive federal funding for drugs dispensed to Medicaid recipients. (Henderson Ex. 3)

Dey's Response: Dey does not dispute that it entered into a Rebate Agreement with the Secretary of Health and Human Services in 1991. Dey further states that it entered into a Rebate Agreement on February 28, 1991 and the terms of the Rebate Agreement applied retroactively to January 1, 1991. (Dey-SOF ¶ 88 (*citing* Reid Decl., Ex. 34))[1]. Dey disputes the remaining statements in US-SOF No. 7 because they are immaterial to the issues before the Court.

8. Dey's principal generic albuterol product is a liquid unit dose solution that is administered via a nebulizer, which is an item of durable medical equipment. (Dey Defendants' Statement of Undisputed Material Facts in Support of Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion for Partial Summary Judgment ("Dey-SOF") ¶ 11.)

Dey's Response: Dey does not dispute US-SOF No. 8.

9. In early 1992 Dey received FDA approval of an abbreviated new drug application for albuterol unit dose solution, 0.083%. Dey launched the generic product in March 1992 and became the first pharmaceutical manufacturer to launch a generic albuterol unit dose solution. Dey was the only generic manufacturer in the albuterol unit dose solution market for over one year after launch. (Dey-SOF ¶¶ 12-13.)

Dey's Response: Dey does not dispute US-SOF No. 9. Dey further states that not only was Dey's albuterol product the first generic unit dose albuterol to market, it was the first BAC-preservative-free albuterol unit dose solution on the market. (Dey-SOF ¶ 14 (*citing* Reid Decl., Ex. 1; Marrs Aff. ¶ 17)).

10. Dey launched its multi-dose albuterol product in March 1996, and its metered dose inhaler albuterol product in November 1996. (Dey-SOF ¶ 21.)

Dey's Response: Dey does not dispute US-SOF No. 10 with regard to the launch of Dey's multi-dose albuterol product, but disputes the launch month for Dey's metered dose inhaler albuterol product. Dey's metered dose inhaler product was launched in January 1996.

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[1] Dey relies upon documents attached to the Declaration of Sarah L. Reid in Support of Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion for Partial Summary Judgment (Dkt. 6184) (annexing exhibits 1-296), and the Declaration of Sarah L. Reid in Support of Dey's Opposition to Plaintiffs' Motion for Partial Summary Judgment filed concurrently with this response (annexing exhibits 297-418) (collectively, "Reid. Decl. Ex. __"), as well as the declarations of W. David Bradford, Ph.D. ("6/26/09 Bradford Decl.") (Dkt. 6180) and Lauren J. Stiroh, Ph.D. ("6/26/09 Stiroh Decl.") (Dkt. 6182).

(Dey-SOF ¶ 46). Plaintiffs admit that the launch date was January 1996 in their response to Dey-SOF No. 21.

11. In addition to albuterol, Dey was also pursuing opportunities to launch other generic respiratory inhalation solutions in the late 1980s and early 1990s. Dey thus submitted an Abbreviated New Drug Application ("ANDA") for cromolyn sodium, which was the next generic inhalation solution coming off patent. (Dey-SOF ¶27.)

Dey's Response: Dey does not dispute US-SOF No. 11, but notes that the evidence supporting this statement is contained in both Dey-SOF Nos. 27-28.

12. Cromolyn sodium ("cromolyn") is a prophylactic respiratory inhalation drug used to treat patients with bronchial asthma. Dey's generic cromolyn product is a liquid unit dose solution that is administered via a nebulizer, which is a piece of durable medical equipment. (Dey-SOF ¶29.)

Dey's Response: Dey does not dispute US-SOF No. 12.

13. Dey launched its cromolyn product in May 1994. As with unit dose albuterol, Dey was the first generic cromolyn on the market. (Dey-SOF ¶¶ 30-31.)

Dey's Response: Dey does not dispute US-SOF No. 13.

14. Dey stopped manufacturing cromolyn in February 2008. (Dey-SOF ¶ 32.)

Dey's Response: Dey does not dispute US-SOF No. 14. Dey further states that it stopped manufacturing cromolyn in February 2008 because it was unable to sustain a profit on sales. (Dey-SOF No. 32 (*citing* Marrs Aff. ¶ 35)).

15. Ipratropium bromide ("ipratropium") is a respiratory inhalation drug used for the maintenance treatment of bronchospasms associated with Chronic Obstructive Pulmonary Disease ("COPD"), which is a term used to describe a number of airway diseases, including both chronic bronchitis and emphysema. (Dey-SOF ¶34.)

Dey's Response: Dey does not dispute US-SOF No. 15. Dey further states that ipratropium is classified as an anticholinergic bronchodilator because it works by preventing the bronchial smooth muscle from constricting. (Dey-SOF No. 35 (*citing* Marrs Aff. ¶ 37; Reid Decl., Ex. 10)).

16. In January 1997, Dey launched a sterile generic unit dose ipratropium bromide solution. (Henderson Ex. 4) Dey's generic ipratropium product is a unit dose liquid solution that is administered via a nebulizer, which is a piece of durable medical equipment. Dey continues to sell ipratropium. (Dey-SOF ¶¶ 36-38.)

Dey's Response: Dey does not dispute US-SOF No. 16. Dey further states that it continues to sell ipratropium at a close to break even profit level. (Dey-SOF No. 38 (*citing* Marrs Aff. ¶ 39)).

17. The Complaint alleges claims against Dey arising from reimbursement by Medicare and Medicaid programs to providers for dispensing varying dosages, concentrations, and sizes of Dey's albuterol sulfate, cromolyn sodium, and ipratropium bromide (the "Subject Drugs"). (Complaint; Dey-SOF ¶ 43.) All of the Subject Drugs are generic drugs. (Dey-SOF ¶ 44.)

Dey's Response: Dey does not dispute US-SOF No. 17.

18. The Subject Drugs are or were sold under a number of National Drug Codes (NDCs). NDCs are 11-digit codes that uniquely identify the drug by manufacturer, active ingredient, and package size. Dey has assigned successor NDCs to a number of its products due to changes in the packaging. (Dey-SOF ¶ 45.)

Dey's Response: Dey does not dispute US-SOF No. 18.

19. The following are the NDCs for the Subject Drugs with date of first and last shipment date as applicable:

Subject Drug	Formulation	Strength/Package Size	NDC	First Shipment Date	Last Shipment Date
Albuterol Sulfate	metered dose inhaler	17g	49502-0303-17	Q1 1996	Q2 2000
Albuterol Sulfate	metered dose inhaler	17g, 90 mcg	49502-0333-17	Q3 2000	Q1 2003
Albuterol Sulfate	MDI refill	17g	49502-0303-27	Q4 1996	Q2 2000
Albuterol Sulfate	MDI refill	17g	49502-0333-27	None	None
Albuterol Sulfate	multi dose solution	.5%,20 ml	49502-0196-20	Q1 1996	Q1 2000
Albuterol Sulfate	multi dose solution	.5%,20 ml	49502-0105-01	Q3 1999	Q3 2003
Albuterol Sulfate	unit dose solution	.083%, 3 ml, 25s	49502-0697-03	Q1 1992	Q2 2004
Albuterol	unit dose	.083%, 3 ml,	49502-0697-24	Q1 2004	Current

Subject Drug	Formulation	Strength/Package Size	NDC	First Shipment Date	Last Shipment Date
Sulfate	solution	25s			
Albuterol Sulfate	unit dose solution	.083%, 3 ml, 30s	49502-0697-33	Q4 1993	Q1 2004
Albuterol Sulfate	unit dose solution	.083%, 3 ml, 30s	49502-0697-29	Q1 2004	Current
Albuterol Sulfate	unit dose solution	.083%, 3 ml, 30s	49502-0697-30	Q1 2005	Current
Albuterol Sulfate	unit dose solution	.083%, 3 ml, 60s	49502-0697-60	Q2 1992	Q3 2004
Albuterol Sulfate	unit dose solution	.083%, 3 ml, 60s	49502-0697-61	Q1 2004	Current
Cromolyn Sodium	unit dose solution	20 mg, 2ml, 120s	49502-0689-12	Q2 1994	Q1 2004
Cromolyn Sodium	unit dose solution	20 mg, 2ml, 60s	49502-0689-02	Q2 1994	Q3 2004
Cromolyn Sodium	unit dose solution	20 mg, 2ml, 60s	49502-0689-61	Q1 2004	Q1 2008
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 25s	49502-0685-03	Q1 1997	Q1 2004
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 25s	49502-0685-24	Q1 2004	Q2 2006
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 25s	49502-0685-26	Q2 2006	Current
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 30s	49502-0685-33	Q3 1997	Q1 2004
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 30s	49502-0685-29	Q1 2004	Q3 2005
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 30s	49502-0685-31	Q2 2005	Current
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 30s	49502-0685-30	Q1 2005	Current
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 60s	49502-0685-60	Q1 1997	Q2 2004
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 60s	49502-0685-61	Q1 2004	Q3 2008
Ipratropium Bromide	unit dose solution	.02%, 2.5 ml, 60s	49502-0685-62	Q2 2005	Current

(Complaint ¶ 29; Dey-SOF ¶ 46; Expert Report of Simon D. Platt (not filed), Summary 5).

Dey's Response: Dey disputes US-SOF No. 19 to the extent it is inconsistent with Dey-SOF No. 46, and specifically disputes the cited evidence other than Dey-SOF No. 46.

Specifically, Dey disputes that the First Shipment Date for 49502-0333-17 is Q3 2000. As stated in Dey-SOF No. 46, the First Shipment Date for 49502-0333-17 is Q1 2000. Dey further disputes that the First Shipment Date for 49502-0105-01 is Q3 1999. As stated in Dey-SOF No. 46, the First Shipment Date for 49502-0105-01 is Q2 1999. Dey further disputes that the First Shipment Date for 49502-0689-02 is Q2 1994. As stated in Dey-SOF No. 46, the First Shipment Date for 49502-0689-02 is Q1 1994.

20. NDC #49502-0333-17 was a successor to NDC #49502-0303-17 and consisted of the same drug in changed packaging. (Henderson Ex. 5.)

Dey's Response: Dey does not dispute US-SOF No. 20, except to state that NDC #49502-0333-17 was manufactured by Armstrong Pharmaceuticals and later Medeva Pharmaceuticals for Dey and NDC #49502-0303-17 was manufactured by Glaxo Wellcome for Dey.

21. NDC #49502-0333-27 was a successor to NDC #49502-0303-27 and consisted of the same drug in changed packaging. (*Id.*)

Dey's Response: Dey disputes US-SOF No. 21. NDC#49502-0333-27 was never sold by Dey. (Declaration of Sarah L. Reid in Support of Dey's Opposition to Plaintiffs' Motion for Partial Summary Judgment, dated August 28, 2009 ("Reid Decl."), Ex. 297, Deposition of Gary Walker, dated 7/9/08, ("Walker Dep."), at 429:5-21).

22. NDC #49502-0105-01 was a successor to NDC #49502-0196-20 and consisted of the same drug in changed packaging. (Henderson Ex. 6.)

Dey's Response: Dey does not dispute US-SOF No. 22, except to state that NDC #49502-0105-01 was manufactured by Bausch & Lomb Pharmaceuticals for Dey and NDC #49502-0196-20 was manufactured by Glaxo Wellcome for Dey.

23. NDC #49502-0697-24 was a successor to NDC #49502-0697-03 and consisted of the same drug in changed packaging. (Henderson Ex. 7.)

Dey's Response: Dey does not dispute US-SOF No. 23.

24. NDC #49502-0697-29 was a successor to NDC #49502-0697-33 and consisted of the same drug in changed packaging. (*Id.*)

Dey's Response: Dey does not dispute US-SOF No. 24.

25. NDC #49502-0697-30 was a successor to NDC #49502-0697-33 and consisted of the same drug in changed packaging. (*id.*)

Dey's Response: Dey does not dispute US-SOF No. 25.

26. NDC #49502-0697-61 was a successor to NDC #49502-0697-60 and consisted of the same drug in changed packaging. (*id.*)

Dey's Response: Dey does not dispute US-SOF No. 26.

27. NDC #49502-0689-61 was a successor to NDC #49502-0689-02 and consisted of the same drug in changed packaging. (*id.*)

Dey's Response: Dey does not dispute US-SOF No. 27.

28. NDC #49502-0685-24 was a successor to NDC #49502-0685-03 and consisted of the same drug in changed packaging. (*id.*)

Dey's Response: Dey does not dispute US-SOF No. 28.

29. NDC #49502-0685-26 was a successor to NDC #49502-0685-24 and consisted of the same drug in changed packaging. (Dey-SOF ¶ 46.)

Dey's Response: Dey does not dispute US-SOF No. 29.

30. NDC #49502-0685-29 was a successor to NDC #49502-0685-33 and consisted of the same drug in changed packaging. (*id.*)

Dey's Response: Dey does not dispute US-SOF No. 30.

31. NDC #49502-0685-31 was a successor to NDC #49502-0685-29 and/or NDC #49502-0685-33 and consisted of the same drug in changed packaging. (Henderson Ex. 8.)

Dey's Response: Dey does not dispute US-SOF No. 31.

32. NDC #49502-0685-30 was a successor to NDC #49502-0685-31 and consisted of the same drug in changed packaging. (Henderson Ex. 9.)

Dey's Response: Dey does not dispute US-SOF No. 32.

33. NDC #49502-0685-61 was a successor to NDC #49502-0685-60 and consisted of the same drug in changed packaging. (Henderson Ex. 7.)

Dey's Response: Dey does not dispute US-SOF No. 33.

34. NDC #49502-0685-62 was a successor to NDC #49502-0685-61 and consisted of the same drug in changed packaging. (Henderson Ex. 8.)

Dey's Response: Dey does not dispute US-SOF No. 34.

35. Dey sells the Subject Drugs to various classes of customers, including wholesalers, retail generic distributors, chain pharmacies, independent pharmacies, homecare pharmacies, hospitals, and long term care facilities. (Dey-SOF ¶ 47.)

Dey's Response: Dey does not dispute US-SOF No. 35.

36. Dey sells its drugs through two primary distribution channels - direct sales and indirect sales. In a direct sale, Dey invoices its customer for a product and then ships the product directly from Dey's distribution center to that customer. All sales to wholesalers as well as all sales to purchasers who can take delivery at their own distribution center are direct sales. Dey-SOF ¶¶ 48 - 50.

Dey's Response: Dey does not dispute US-SOF No. 36.

37. An indirect sale is typically a sale that takes place between Dey's wholesale customer and one of Dey's contract customers who does not take direct delivery of the product from Dey. In an indirect sale with a contract, Dey negotiates a contract price with an indirect customer. The contract price sets forth the price between Dey and the indirect customer, not the price between the indirect customer and the wholesaler. Dey-SOF ¶¶ 51 - 53. The indirect customer purchases Dey's product from the wholesaler.

Dey's Response: Dey disputes US-SOF No. 37 to the extent it is inconsistent with and mischaracterizes Dey-SOF Nos. 51-53, and thus the evidence cited by Plaintiffs does not support the statements contained in US-SOF No. 37. Specifically, Dey-SOF No. 51 does not provide that "[a]n indirect sale *is typically* a sale that takes place between Dey's wholesale customer and one of Dey's contract customers who does not take delivery of the product from Dey" as Plaintiffs assert. Rather, Dey-SOF No. 51 provides that "[a]n indirect sale *can be* a sale that takes place between Dey's wholesaler customer and one of Dey's contract customers who does not take delivery of the product from Dey." (Dey-SOF No. 51 (*citing* Reid Decl., Ex. 5, at 90:11-91:8; 103:6-104)). Moreover, wholesalers can also make indirect sales to customers with

no contracts with Dey. In indirect sales where there is no contract with Dey, Dey has no visibility into the price paid by the wholesaler's customer. (Dey-SOF No. 54 (*citing* Reid Decl., Ex. 16, at 104:10-12)).

Dey-SOF No. 52 provides that "[i]n an indirect sale with a contract, Dey negotiates a contract price with an indirect customer *that will ultimately purchase Dey's product from a wholesaler*." (Dey-SOF No. 52 (*citing* Reid Decl., Ex. 5, at 90:11-91:1; 91:5-8; Reid Decl., Ex. 15, at 456:5-457:7)).

With respect to Dey-SOF No. 53, Dey notes that Plaintiffs quote it verbatim as an undisputed fact in US-SOF No. 37, but dispute the same statement contained in Dey-SOF No. 53 in Plaintiffs' Response to Dey-SOF. (*See* Plaintiffs' Response to Dey-SOF No. 53, at pp. 18-19).

38. Virtually all indirect sales are at prices that are lower than Dey's WAC invoice price to the wholesaler. (Henderson Ex. 10, at 104:19-105:10) The wholesaler agrees to honor the contract price. (Henderson Ex. 10, at 106:20-107:3) Because the price paid by the indirect customer is less than the WAC invoice price from Dey to the wholesaler, Dey pays the wholesaler a "chargeback" to make the wholesaler whole. (Henderson Ex. 10, at 105) The chargeback on an indirect sale is typically the difference between the indirect contract price and the WAC on the invoice to the wholesaler.

Dey's Response: REDACTED

39. REDACTED

Dey's Response: REDACTED

40. REDACTED

Dey's Response: REDACTED

41. REDACTED

Dey's Response: REDACTED

42. Dey knows that wholesaler margins are very small. (Henderson Ex. 14; Henderson Ex. 15, at 226:20-227:2)

Dey's Response: Dey disputes US-SOF No. 42 as irrelevant and immaterial to the issues before the Court. Dey also disputes US-SOF No. 42 because it mischaracterizes the content of the document and testimony to which it cites. Dey further disputes Plaintiffs' attempt to confuse wholesaler "markups" or "upcharges" with wholesaler "margins" which are two entirely different concepts. Dey does not dispute that Mr. Hill, a sales representative with no responsibilities for any of the national wholesalers and who was only employed by Dey in 1994-1996, testified that he believed wholesaler upcharges were "within a low single digit." (Henderson Ex. 15, at 226). Dey disputes that Mr. Hill's testimony is accurate or that his knowledge can be imputed to Dey. Indeed, Dey's corporate representative, Pam Marrs, testified that Dey has no visibility to wholesaler markups. (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 78:12-79:10).

Exhibit 14 is a fax memorandum, dated June 20, 1996, and authored by Charles Rice. In the fax memorandum, Mr. Rice makes a passing remark that "[a]pparently, drug wholesalers have decided they can no longer survive on profit margins of 2% - 4%..." (Henderson Ex. 14 at DL-TX-0162679). Dey disputes Plaintiffs' reliance on Exhibit No. 14 because it is not probative of the facts alleged and it is inadmissible hearsay.

43. REDACTED

Dey's Response: REDACTED

44. Dey sells drugs via direct sales to wholesalers pursuant to contracts between Dey and the wholesaler. Some of these contracts are for the supply of drugs that will be sold by the wholesaler through source programs. (Henderson Ex. 17, at 351-353, Dep. Ex. 49.)

Dey's Response: Dey disputes US-SOF No. 44. Dey incorporates its responses to US-SOF Nos. 38 and 39. As stated more fully in responses to US-SOF Nos. 38 and 39, at the time of the transaction between Dey and the wholesaler, Dey does not know to which customers the

wholesaler will sell its drugs, including whether the drugs will be the subject of a "source program," and the final prices to those customers.

Dey disputes that it "sells drugs via direct sales to wholesalers pursuant to contracts between Dey and the wholesaler." As Mr. Johnston, Dey's contracts manager, testified:

> The sale to a wholesaler – and I can certainly mention the biggest – the largest three, AmerisourceBergen, Cardinal, and McKesson, in selling it to them there's no contract involved in that. It's an invoice by invoice, purchase order by purchase order arrangement. Purchase orders come in at the products priced at WAC, invoicing is at WAC.

(Reid Decl., Ex. 306, 12/10/08 Johnston Dep. 32:8-15).

Dey does not dispute that wholesalers have "source programs" and that Dey pays chargebacks to wholesalers, but refers to its responses to US-SOF Nos. 38 and 39 for a more complete and accurate description of the way Dey interacts with wholesalers.

45. Dey contracts with wholesalers for direct sales to the wholesaler at prices below WAC. For example, for a period of time in the 1990s, Dey sales personnel used a "cheat sheet" containing prices at which different classes of customers, including wholesalers, could buy product from Dey. (Henderson Ex. 10, at 150:21-151:13, and Dep. Ex. 18.) Dey sales personnel were authorized to sell product at or above the price shown on the cheat sheet without further authorization. A 1993 cheat sheet accompanying Johnston Ex. 18 shows the prices to the wholesaler class of trade for Dey's albuterol unit dose, packages of 25s and 60s, (NDC #495020697-03 and 49502-0697-60), effective 8/1/1993, as $18.95 and $44.40, respectively. Dey's reported WACs in 1993 Q3 were $25.00 and $54.00, respectively, significantly above the actual wholesale prices shown on the cheat sheet.

Dey's Response: Dey disputes US-SOF No. 45 because it is unsupported by the cited testimony and documents. Plaintiffs cite no support for their assertion that Dey's reported WACs for albuterol unit dose in Q3 1993 were $25.00 and $54.00. Indeed, Plaintiffs' own charts depicting Dey's reported prices for albuterol unit dose show that the reported WACs were actually $18.95 and $44.40 respectively in Q3 1993 – which match the $18.95 and $44.40 WAC prices set forth on the price list (or "cheat sheet") annexed as Exhibit 10. (*See* Henderson

Exhibit 19, at chart A-4 (25 pack pricing) and chart A-6 (60 pack pricing)). There is no discrepancy as Plaintiffs suggest.

In addition, Dey disputes that it "contracts with wholesalers for direct sales to the wholesaler at prices below WAC." As Mr. Johnston testified:

> The sale to a wholesaler – and I can certainly mention the biggest – the largest three, AmerisourceBergen, Cardinal, and McKesson, in selling it to them there's no contract involved in that. It's an invoice by invoice, purchase order by purchase order arrangement. Purchase orders come in at the products priced at WAC, invoicing is at WAC.

(Reid Decl., Ex. 306, 12/10/08 Johnston Dep. 32:8-15). Dey incorporates Dey-SOF Nos. 81-83 as if set forth fully herein.

46. The memorandum at Johnston Ex. 18 includes the statement, "As shown in the chart, Dey's wholesale price change, effective August 1, will keep the reimbursement spread to Dey's advantage." (*Id.*)

Dey's Response: Dey disputes US-SOF No. 46 to the extent that it suggests that Dey did anything improper by reducing its selling prices to meet competition. Dey further states that the price change referenced in the memorandum was a reduction to Dey's WAC (which, as set forth in Dey-SOF Nos. 66-75, signals a reduction in underlying average selling prices) for Dey's albuterol unit dose product, not an increase in AWP. (*See* Henderson Ex. 10). Plaintiffs admit that Dey never increased its AWP for albuterol unit dose, and in fact, admit that the AWP for Dey's albuterol unit dose was lowered to $30.25 sometime in 1994. (*See* US-SOF No. 85). Dey further notes that the reduction in Dey's AWP from $32.30 to $30.25 in 1994 would have eliminated any reimbursement spread "advantage" that Dey may have had vis-à-vis Copley. (*See* Henderson Ex. 10). Dey therefore disputes US-SOF No. 46 as immaterial to the issues before the Court.

47. Similarly, in 2002, a representative of Cardinal Health wrote to Dey requesting that Dey verify all contract prices in effect between Cardinal and Dey, including contracts

> relating to Cardinal's sales programs called PreferredSOURCE, ManagedSOURCE, Generic Alliance, Cardinal GAP/Winn Dixie, Mail Order Alliance, NeighborCare LTC, LTC Generics, Owen Alliance, Access Expanded and Access Acute/Continuum. (Henderson Ex. 17, at 49.) The request included a spreadsheet that set forth the Dey-Cardinal contract prices for Dey drugs, as well as the AWPs and WACs (referred to in the spreadsheet as "NIFO," according to p. 2 of the exhibit).

Dey's Response: Dey disputes US-SOF No. 47 because it is not supported by the document cited. According to Henderson Exhibit 17, on August 2002, a Cardinal Health representative wrote to Dey and requested that Dey verify the contract prices that are available to Cardinal Health's various source program members, not to Cardinal Health itself. Dey disputes that it contracts with wholesalers for direct sales to the wholesaler at prices below WAC. As Mr. Johnston testified:

> The sale to a wholesaler – and I can certainly mention the biggest – the largest three, AmerisourceBergen, Cardinal, and McKesson, in selling it to them there's no contract involved in that. It's an invoice by invoice, purchase order by purchase order arrangement. Purchase orders come in at the products priced at WAC, invoicing is at WAC.

(Reid Decl., Ex. 306, 12/10/08 Johnston Dep. 32:8-15).

Dey does not dispute that wholesalers have "source programs" or "sales programs" and that Dey pays chargebacks to wholesalers, but refers to its responses to US-SOF Nos. 38 and 39 for a more complete and accurate description of the way Dey interacts with wholesalers.

48. The spreadsheet shows a comparison of contract prices and WACs for approximately 168 distinct NDC/contract prices. Every one of the contract prices is below the WAC. The spreads between the contract price and the WAC range from 12% to 53%. (Henderson Ex. 18.)

Dey's Response: Dey disputes US-SOF No. 48 because it does not refer specifically to the drugs at issue. Dey also disputes US-SOF No. 48 to the extent that it implies that Dey provided contract prices to wholesalers for direct sales to the wholesalers at prices below WAC because

this assertion is contradicted by Mr. Johnston's testimony. (Reid Decl., Ex. 306, 12/10/08 Johnston Dep. 32:8-15). Dey incorporates its responses to US-SOF Nos. 38, 39, and 47.

49. Dey representative Russell Johnston signed the verification of the contract prices. (Henderson Ex. 17.)

Dey's Response: Dey does not dispute that Mr. Johnston signed Exhibit 17, but disputes US-SOF No. 49 because it is immaterial to the issues before the Court.

50. REDACTED

Dey's Response: REDACTED

51. REDACTED

Dey's Response: REDACTED

52. REDACTED

Dey's Response: REDACTED

53. REDACTED

Dey's Response: REDACTED

54. In the sales transaction data produced by Dey, gross sales for all the Subject Drugs, prior to adjustments for chargebacks, rebates, and other miscellaneous adjustments, total approximately $2.488 billion. (Henderson Ex. 19, at ¶ 13.)

Dey's Response: Dey disputes US-SOF No. 54 as unsupported by the evidence cited. For the purposes of this motion, Dey does not dispute that Mr. Platt's calculations are mathematical calculations of what Mr. Platt purports to be gross sales for all the Subject Drugs, but disputes the accuracy of Mr. Platt's calculations to the extent they conflict with Dey's own calculations of its gross sales for the Subject Drugs as set forth in monthly sales reports and other reports generated by Dey's finance department. (*See, e.g.*, Reid Decl., Ex. 312; Ex. 313; Ex. 314; Ex. 315; Ex. 316; Ex. 317; Ex. 318; Ex. 319).

55. In the sales transaction data produced by Dey, the data reflects approximately $480.6 million in chargebacks (19.3% of gross sales), approximately $1,392 million in

rebates (5.6% of gross sales), and $46.0 million (1.8% of gross sales) in other miscellaneous adjustments. (*Id.*)

Dey's Response: Dey disputes US-SOF No. 55 as unsupported by the evidence cited. For the purposes of this motion, Dey does not dispute that Mr. Platt's calculations are mathematical calculations of what Mr. Platt purports to be total chargebacks, rebates, and other miscellaneous adjustments for all the Subject Drugs, but disputes the accuracy of Mr. Platt's calculations to the extent they conflict with Dey's own calculations of the figures as set forth in monthly sales reports and other reports generated by Dey's finance department. (*See, e.g.*, Reid Decl., Ex. 312; Ex. 313; Ex. 314; Ex. 315; Ex. 316; Ex. 317; Ex. 318; Ex. 319).

56. The indirect transaction data, which reflects sales for which chargebacks were paid, shows gross sales prior to adjustments for chargebacks of $1.303 billion.

Dey's Response: Dey disputes US-SOF No. 56 as unsupported by the evidence cited. For the purposes of this motion, Dey does not dispute that Mr. Platt's calculations are mathematical calculations of what Mr. Platt purports to be gross sales for all the Subject Drugs, but disputes the accuracy of Mr. Platt's calculations to the extent they conflict with Dey's own calculations of gross sales as set forth in monthly sales reports and other reports generated by Dey's finance department. (*See, e.g.*, Reid Decl., Ex. 312; Ex. 313; Ex. 314; Ex. 315; Ex. 316; Ex. 317; Ex. 318; Ex. 319).

57. In the indirect transaction data, chargebacks total approximately $441.4 million (33.9% of gross sales). (Henderson Ex. 19, at 1115.)

Dey's Response: Dey disputes US-SOF No. 57 as unsupported by the evidence cited. For the purposes of this motion, Dey does not dispute that Mr. Platt's calculations are mathematical calculations of what Mr. Platt purports to be total chargebacks for all the Subject Drugs, but disputes the accuracy of Mr. Platt's calculations to the extent they conflict with Dey's own calculations of total chargebacks as set forth in monthly sales reports and other reports

generated by Dey's finance department. (*See, e.g.*, Reid. Decl., Ex. 312; Ex. 313; Ex. 314; Ex. 315; Ex. 316; Ex. 317; Ex. 318; Ex. 319).

58. When Dey launched a drug, it reported its internally determined AWPs and WACs for drugs to certain publishers and data services, including First Data Bank ("FDB") (which maintains the National Drug Data File), Medi-Span, and Red Book (the "Publishers"). (Henderson Ex. 19A (Dey Answers to Interrogatories, Response No. 1)); Dey-SOF ¶ 76.)

Dey's Response: Dey disputes US-SOF No. 58 because it does not relate specifically to any of the drugs at issue. Dey further states that it reported its AWP for the Subject Drugs to the publishers so that the Subject Drugs could be recognized by the industry and third party payors as generics. At launch, pricing for a first-to-market generic, like Dey's albuterol unit dose, is set in relationship to the brand AWP. (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 129:22-130:11). Dey's practice of establishing AWPs for the Subject Drugs at a percentage lower than the therapeutically equivalent brand AWPs was consistent with industry practice. (Reid Decl., Ex. 305, 7/10/08 Dey Dep. 460:2-8). According to Patricia Kay Morgan, former Manager of Editorial Services at First DataBank, there was a "perception in the industry" that a generic drug had to be priced at least 10 percent less than the brand price. (Reid Decl., Ex. 320, Deposition of Patricia Kay Morgan, dated 11/30/07 ("11/30/07 Morgan Dep."), at 21:4-18).

WAC is Dey's invoice price to wholesalers. (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 75:22-76:3; 144:21-145:1; Ex. 305, 7/10/08 Dey Dep. 537:9-15; Ex. 306, 12/10/08 Johnston Dep. 29:6-12; 31:14-16; Ex. 307, 12/11/08 Johnston Dep. 501:2-17; Ex. 308). Ms. Marrs explained: "The WAC that's reported is the invoice price to the customer – to the wholesaler." (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 144:21-145:1).

Dey regularly updated its WAC in a manner that directly reflected underlying pricing activity. (Reid Decl., Ex. 321, Deposition of Robert Mozak, dated 4/30/02 ("4/30/02 Mozak Dep."), at 372:11-20). Ms. Marrs explained that as market prices decline, Dey has also reduced

its reported WAC. (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 136:16-21). Moreover, Dey notified price reporting services and state Medicaid offices as soon as the WAC was lowered. (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 137:6-17).

59. After the launch of a drug, Dey periodically reported its AWPs and WACs to the Publishers. Dey reported prices to the Publishers when there was a price change. (Dey Answers to Interrog., Response No. l; (Henderson Ex. 20, at 104.)

Dey's Response: Dey disputes US-SOF No. 59 because it does not relate specifically to any of the drugs at issue. Dey incorporates its response to US-SOF Nos. 58 and 60 as if fully set forth herein.

60. Dey expected that the WACs and AWPs that it reported to First DataBank and the Red Book would be the WACs and AWPs that First DataBank and the Red Book would publish. (Henderson Ex. 21, at 467:19-467:22; Henderson Ex. 10, at 71.)

Dey's Response: Dey disputes US-SOF No. 60 because it does not relate specifically to any of the drugs at issue. Dey reported AWP and WAC prices to the drug pricing compendia, but what happened to those prices after they were received by the compendia was in the control of the compendia, and not Dey. A review of the prices published by the various compendia show that the prices were updated at various times, and not all of the compendia list the same price at the same time. (Reid Decl., Ex. 322 at 2). Moreover, Ms. Marrs testified that Dey did not control the publication of Dey's prices and that Dey could not know if the published prices accurately reflected those reported by Dey:

> A. …. We do not – we do not now – and I'm not sure if we even did then, other than this piece of paper we got from them actually physically look in the published document to see if our prices were input correctly.
>
> Q. But Dey does know that the prices that are reported in First DataBank, Medispan, and Redbook are the prices that were reported to it by Dey; correct?
>
> A. No. That's what I was trying to explain. In the early years they would send us a piece of paper back, not the – not the published document, but a confirmation form, where we would look at it, it appears from the

> documentations I've looked at, and validate, that that was, in fact, what we sent them. That doesn't happen any longer. What we do now is we send them a letter notifying them of a price change, and we ask them to sign off and send back to us a confirmation that they received the information. We do not then go and – verify that they've posted the correct amount, which became obvious when this whole issue happened with the generic products in 2003, where they lowered our AWP. We didn't actually know anything about it until customers started calling and complaining.

(Reid Decl., Ex. 300, 5/15/08 Dey Dep. 135:1-136:10).

61. Dey continues to report WAC and AWP to FDB. (Henderson Ex. 22, at 303-304; Henderson Ex. 23, at 84.)

Dey's Response: Dey disputes US-SOF No. 61 because it does not relate specifically to any of the drugs at issue. Dey further states that it continues to regularly update its WAC in a manner that directly reflects underlying pricing activity. Ms. Marrs explained that as market prices decline, Dey has also reduced its reported WAC. (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 136:16-21). Moreover, Dey notified price reporting services and state Medicaid offices as soon as the WAC was lowered. (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 137:6-17).

Dey disputes US-SOF No. 61 to the extent that certain of the Subject Drugs have been discontinued and thus pricing is no longer reported for those drugs. Dey stopped selling multi dose albuterol in mid-2003, metered dose inhaler albuterol in early 2003, and cromolyn in February 2008. (6/26/09 Marrs Aff. ¶¶ 27, 29, and 35).

62. Dey supplies WAC and AWP to FDB because State Medicaid programs use it as a reference guide for pricing in the industry. (Henderson Ex. 24, at 299-300.)

Dey's Response: Dey disputes US-SOF No. 62 because it is not supported by the testimony cited and mischaracterizes the testimony of Mr. Mozak. The cited testimony references Dey's reasons for reporting WAC to First DataBank, and does not relate to AWP whatsoever:

> Q. Can you give me any reason whatsoever that Dey submits its WAC prices to First DataBank other than the fact that it's always done so?

> A. No. We've always done it.
>
> Q. And you're – sorry.
>
> A. We've always done it, and we'll likely continue to do it.
>
> Q. You're the executive vice-president for sales and marketing of Dey Laboratories, correct, sir?
>
> A. Uh-huh.
>
> Q. And it's your testimony and you're telling the court and the jury that you don't know of any reason whatsoever that Dey Laboratories supplies its WAC prices to First DataBank except that it's always done so. Is that your testimony?
>
> A. Well, I also believe now that it is also utilized by the State as a reference guide; so that would be another reason to submit it.

(*See* Henderson Decl., Ex. 24, at 299:10-300:3).

Moreover, Dey's regular reporting of reductions to WAC benefited the Medicaid and Medicare programs because Dey updated its WACs in a manner that directly reflected underlying pricing activity. (*See* Dey's Responses to US-SOF Nos. 58, 60). Ms. Marrs explained that as market prices decline, Dey has also reduced its reported WAC. (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 136:16-21). Moreover, Dey notified price reporting services and state Medicaid offices as soon as the WAC was lowered. (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 137:6-17).

Dey reported its AWP for the Subject Drugs to the publishers so that the Subject Drugs could be recognized by the industry and third party payors as generics. (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 129:22-130:11).

Dey also disputes US-SOF No. 62 because it does not relate specifically to any of the drugs at issue.

63. REDACTED

Dey's Response: REDACTED

64. REDACTED

Dey's Response: REDACTED

65. From 1993 to 2001 or 2002, Robert Mozak, Dey's former vice president of Sales and Marketing, and various employees in Dey's marketing department, including former employees Debra Bronstein, Helen Burnham Selenati, and Todd Galles, participated in recommending, or determining AWP and WAC prices for the Subject Drugs. Since 2001 or 2002, the persons responsible for reviewing AWP and WAC pricing have included various members of the contracts, sales, marketing, and finance departments, including Russell Johnston. (Henderson Ex. 19A; Henderson Ex. 20, at 104; Henderson Ex. 10, at 55-56.)

Dey's Response: Dey does not dispute the statements contained in US-SOF No. 65, but notes that Plaintiffs' citations to Exhibits 10 and 20 do not support the statements contained therein. Specifically, US-SOF No. 65 discusses who was responsible for "recommending," "determining," or "reviewing" WAC and AWP pricing, but the citations to Exhibit Nos. 10 and 20 discuss who was responsible for "reporting" AWP and WAC pricing. (*See* Henderson Ex. 20, at 104; Henderson Ex. 10, at 55-56).

66. When Dey launched its ipratropium bromide products NDC 49502-0685-03 and 49502-0685-60 in January 1997, Dey reported to FDB and Red Book AWPs of $44.10 and $105.60, respectively. (Henderson Ex. 28, at Dep. Ex. 275; Henderson Ex. 4, at DL-TX0093102; Henderson Ex. 30, at 07116.) Red Book published those prices. (Declaration of George B. Henderson, II Submitting Exhibits in Support of Motions for Partial Summary Judgment ("Henderson Common") Ex. 3, ¶ 26 & Ex. C.) First DataBank published prices of $44.00 and $105.60, respectively. (Henderson Ex. 19, at Summary A9 and Al 1.)

Dey's Response: Dey does not dispute the statements contained in US-SOF No. 66, but incorporates its responses to US-SOF Nos. 58 and 60 as if fully set forth herein.

Dey further states that US-SOF No. 66 is incomplete because it does not reference Dey's reporting of WAC for its ipratropium products at launch and over time. Specifically, as demonstrated by Plaintiffs' own chart A9 submitted in support of US-SOF No. 66, Dey reduced its reported WACs for ipratropium over time in a manner that directly reflected underlying pricing activity. (Henderson Ex. 19, at Summary A9; *see also* Dey-SOF Nos. 73-79). The

reduced WACs were available to CMS and to State Medicaid offices via Red Book, First Databank, and Medispan. (*See* Dey-SOF No. 76).

67. Helen Burnham Selenati, a Marketing Manager at Dey from 1990 to 1995, had responsibility for reporting Dey's AWPs and WACs to the pricing compendia during her tenure at Dey. She knew that the Publishers published those numbers in their databases, Red Book and Blue Book. (Henderson Ex. 1, at 13-15, 42-44.)

Dey's Response: Dey disputes US-SOF No. 67 because it is incomplete and thus mischaracterizes Ms. Burnham Selenati's testimony concerning her understanding of price reporting. Ms. Burnham Selenati testified that drug companies had to have an AWP if they wanted their drugs to be published in the databases. (Reid Decl., Ex. 325, Deposition of Helen Burnham Selenati, dated 5/5/05 ("5/5/05 Burnham Selenati Dep."), at 280:15-19). Ms. Burnham Selenati further testified that she never obtained a copy of First DataBank publications to see what prices First DataBank actually reported. (Reid Decl., Ex. 325, 5/5/05 Burnham Selenati Dep. 453:7-12). Dey does not dispute that Ms. Burnham Selenati testified that she had responsibility for price reporting during her tenure at Dey. Dey also notes that Ms. Burnham Selenati left Dey in August 1995. (Reid Decl., Ex. 325, 5/5/05 Burnham Selenati Dep. 233:7-9).

68. On May 30, 1995, Dey reported to First DataBank WAC prices for its Albuterol Sulfate Unit Dose Solution, 0.083%, 3ml, as follows:

NDC	PRODUCT DESCRIPTION	SIZE	UNITS PER CARTON	AWP	WAC
49502-697-03	Albuterol Sulfate Inhalation Solution 0.083%	3 mL	25	$30.25	$24.75
49502-697-33	Albuterol Sulfate Inhalation Solution 0.083%	3 mL	30	$36.30	$29.70
49502-697-60	Albuterol Sulfate Inhalation Solution 0.083%	3 mL	60	$72.60	$59.40

(Henderson Ex. 31; Henderson Ex. 32, at FDB00918.)

Dey's Response: Dey disputes US-SOF No. 68 because it is incomplete and therefore mischaracterizes the evidence on the events surrounding the change in the First DataBank WACs

for Dey's albuterol unit dose products on or about May 30, 1995. The circumstances surrounding the WAC change for albuterol unit dose in May 1995 raise multiple, hotly contested issues of material fact. The Medispan and Red Book WACs for these products were not changed. (6/26/09 Stiroh Decl., Figures E-G).

Dey further states that, sometime prior to August 1994, Dey's customer Pharmacy Factors informed Ross Uhl, a Dey sales representative, that Pharmacy Factors was going to switch some of its patients to Warrick's unit dose albuterol product because Warrick's product had a more favorable reimbursement rate in Florida and Texas. (Reid Decl., Ex. 326, Deposition of Ross Uhl, dated 2/24/03 ("Uhl Dep."), at 63:3-64:19). Other customers complained to Dey about the differential between Dey's and Warrick's WAC for albuterol unit dose. (Reid Decl., Ex. 326, Uhl Dep. 62:5-12, 73:7-21).

From August 1994 to May 1995, Dey considered various ways to deal with the situation. (Reid Decl., Ex. 325, 5/5/05 Burnham Selenati Dep. 359:3-8). Initially, Dey called First DataBank to try to have Warrick's product reclassified as a branded product since Warrick's WAC was so high. (Reid Decl., Ex. 327, Deposition of Helen Burnham Selenati, dated 5/4/05 ("5/4/05 Burnham Selenati Dep."), at 97:19-98:4). This was not successful. (Reid Decl., Ex. 327, 5/4/05 Burnham Selenati Dep. 98:3-4).

On August 8, 1994, Carrie Jackson, who worked in the marketing department and reported directly to Ms. Burnham Selenati, contacted Jerry Wells, the pharmacy director at Florida Medicaid to discuss the problem with the higher spread created by Warrick's high WAC price as compared to Dey's:

> On Monday, August 8, 1994, I spoke with Jerry Wells at the Florida Medicaid office regarding albuterol usage. There is a larger volume of usage for the Warrick product as the following formula for Medicaid reimbursement shows:

* * *

> As the above will show, there is a larger spread for reimbursement purposes on the Warrick product. Jerry Wells stated that other companies have brought similar situations to him on a variety of Warrick products. Jerry would like to discuss the situation further with Ross and can be reached at (904) 487-4441.

(Reid Decl., Ex. 328).

Ross Uhl testified that he contacted Wells sometime in 1994-95 to inform him of Warrick's high WAC price for albuterol unit dose. According to Uhl, Wells responded, "There's nothing I can do about it. They just go by what they tell us. We just pay what is reported to Blue Book or Red Book." (Reid Decl., Ex. 326, Uhl Dep. 65:21-25). When Uhl informed Wells that Warrick's WAC price was incorrect, Wells stated that "Warrick will have to call us and get that changed." (Reid Decl., Ex. 326, Uhl Dep. 66:3-4).

On May 30, 1995, Helen Burnham Selenati, Dey's marketing manager, sent a fax to Beth Raider of Price Alert and Pharmacy Blue Book Update, in which Dey changed the WAC for Dey's albuterol unit dose product from $14.50 to $24.75. (*See* Henderson, Ex. 32; Reid Decl., Ex. 325, 5/5/05 Burnham Selenati Dep. 361:1-11). According to a memorandum authored by Ms. Burnham Selenati, the purpose of the WAC change was to make Dey's "updated WAC values…in line with the Warrick WAC values provided by First DataBank and should level the playing field for Medicaid reimbursement." (Henderson Ex. 64).

None of the sales and marketing personnel that were shown a copy of Ms. Burnham Selenati's May 1995 memorandum during their depositions recalled ever receiving the document in 1995 or of being aware that Dey's WAC for albuterol unit dose was changed in First DataBank's publications. Specifically, seven Dey employees testified that they never saw the May 30, 1995 Memorandum and were unaware that Dey's WAC was ever changed in 1995. (Reid Decl., 329, Deposition of Cynthia Collie, dated 2/19/03 ("2/19/03 Collie Dep."), at 171:2-

10; Ex. 330, Deposition of Robert Ellis, dated 2/10/03 ("Ellis Dep."), at 216:11-17; Ex. 331, Deposition of Eve Fagrell Gmeiner, dated 1/20/03 ("Gmeiner Dep."), at 183:21-184:6, 232:7-17; Ex. 332, Deposition of Charles Rice, dated 10/30/01 ("10/30/01 Rice Dep."), at 124:21-125:1; Ex. 333, Deposition of Bruce Tipton, dated 2/13/03 ("2/13/03 Tipton Dep."), at 220:8-14; Ex. 326, Uhl Dep. 54:11-25; Ex. 334, Deposition of Richard Upp, dated 2/14/03 ("Upp Dep."), at 129:17-130:1). Three Dey employees testified that they saw the memo for the first time in 1997 while searching for documents responsive to a subpoena. (Reid Decl., Ex. 335, Deposition of Debra Bronstein, dated 3/11/03 ("Bronstein Dep."), at 70:9-13, 288:14-289:4; Ex. 336, Deposition of Todd Galles, dated 2/6/03 ("2/6/03 Galles Dep."), at 24:3-24, 164:7-11; Ex. 337, Deposition of Robert Mozak, dated 11/1/01 ("11/1/01 Mozak Dep."), at 187:19-23; Ex. 338, Deposition of Robert Mozak, dated 11/6/2002 ("11/6/02 Mozak Dep."), at 561:17-562:1, 575:2-15).

On September 12, 1995, Rick Speno, a Dey sales representative for the Florida territory, made a visit to Jerry Wells, the pharmacy director of Florida Medicaid. (Reid Decl., Ex. 339). During the visit, Mr. Speno informed Mr. Wells that Dey had updated its WAC for albuterol to be competitive with Warrick. Mr. Speno recorded his discussion with Mr. Wells in his sales account call record of September 12, 1995:

> 69703 WAC updated on First DataBank.
>
> Level playing field w/ Warrick U.D.

(Reid Decl., Ex. 339).

Mr. Speno also recorded his discussion with Mr. Wells in the weekly sales report he provided to his supervisor, Lou Barricelli:

> Previous reimbursement for Warrick unit-dose was higher than Dey 69703 per last update report. This has been corrected and reimbursement is now equal for both products.

(Reid Decl., Ex. 340).

Ms. Burnham Selenati resigned from Dey in August 1995. On December 4, 1995, Eve Gmeiner, a marketing employee at Dey, reported a corrected WAC of $14.50 to Beth Raider of First DataBank and requested that First DataBank correct the WAC price it listed in its publications. (Reid Decl., Ex. 341 at DL-TX-0090595; Ex. 331, Gmeiner Dep. 239:22-244:9; Ex. 336, 2/6/03 Galles Dep. 236:17-238:25).

Accordingly, the incorrect WAC that Ms. Burnham Selenati reported to First DataBank should only have been in effect from May 30, 1995 to December 4, 1995. Dey is not responsible for First DataBank's failure to update the price to the correct price. Ms. Gmeiner and Ms. Bronstein both testified that the price reporting services, including First DataBank, reported incorrect prices at times and failed to update price changes at other times. (Reid Decl., Ex. 335, Bronstein Dep. 299:20-300:8; Ex. 331, Gmeiner Dep. 257:2-7).

69. FDB published the WAC prices reported to it by Dey for the drugs identified in the preceding paragraph , and FDB generally continued to publish those prices until January 1, 1998. (Henderson Ex. 19, at Summaries A5, A12, A13.)

Dey's Response: Dey disputes US-SOF No. 69 because it is incomplete and thus mischaracterizes the evidence on this matter. On December 4, 1995, Dey reported the correct WAC of $14.50 to Beth Raider of First DataBank and requested that First DataBank correct the WAC price it listed in its publications. (Reid Decl., Ex. 341 at DL-TX-0090595; Ex. 331, Gmeiner Dep 239:22-244:9; Ex. 336, 2/6/03 Galles Dep. 236:17-238:25). Dey is not responsible for First DataBank's failure to update the price to the correct price. Ms. Gmeiner and Ms. Bronstein both testified that the price reporting services, including First DataBank, reported incorrect prices at times and failed to update price changes at other times. (Reid Decl., Ex. 335, Bronstein Dep. 299:20-300:8; Ex. 331, Gmeiner Dep. 257:2-7). Dey incorporates its responses to US-SOF Nos. 67-68 as if fully set forth herein.

70. By letter dated December 31, 1997, Dey reported to FDB that, effective January 1, 1998, Dey's WACs for the Albuterol Sulfate Unit Dose Solution, 0.083%, 3ml products were reduced to:

49502-0697-03	Albuterol Sulfate Inhalation Solution 0.083%	$9.50
49502-0697-33	Albuterol Sulfate Inhalation Solution 0.083%	$11.40
49502-0697-60	Albuterol Sulfate Inhalation Solution 0.083%	$22.80

(Henderson Ex. 33.)

Dey's Response: Dey disputes US-SOF No. 70 because it is incomplete and thus mischaracterizes the evidence on this matter. On December 4, 1995, Dey reported the correct WAC of $14.50 to Beth Raider of First DataBank and requested that First DataBank correct the WAC price it listed in its publications. (Reid Decl., Ex. 341 at DL-TX-0090595; Ex. 331, Gmeiner Dep 239:22-244:9; Ex. 336, 2/6/03 Galles Dep. 236:17-238:25). Dey is not responsible for First DataBank's failure to update the price to the correct price. Ms. Gmeiner and Ms. Bronstein both testified that the price reporting services, including First DataBank, reported incorrect prices at times and failed to update price changes at other times. (Reid Decl., Ex. 335, Bronstein Dep. 299:20-300:8; Ex. 331, Gmeiner Dep. 257:2-7). Dey incorporates its responses to US-SOF Nos. 67-68 as if fully set forth herein.

71. Effective January 1, 1998, FDB published the lower WAC prices reported to it by Dey. (Henderson Ex. 18, at Summaries A5, A12, A13.)

Dey's Response: Dey disputes US-SOF No. 71 because it is incomplete and thus mischaracterizes the evidence on this matter. On December 4, 1995, Dey reported the correct WAC of $14.50 to Beth Raider of First DataBank and requested that First DataBank correct the WAC price it listed in its publications. (Reid Decl., Ex. 341 at DL-TX-0090595; Ex. 331, Gmeiner Dep 239:22-244:9; Ex. 336, 2/6/03 Galles Dep. 236:17-238:25). Dey is not responsible for First DataBank's failure to update the price to the correct price. Ms. Gmeiner and Ms.

Bronstein both testified that the price reporting services, including First DataBank, reported incorrect prices at times and failed to update price changes at other times. (Reid Decl., Ex. 335, Bronstein Dep. 299:20-300:8; Ex. 331, Gmeiner Dep. 257:2-7). Dey incorporates its responses to US-SOF Nos. 67-68 as if fully set forth herein.

72. The United States' expert, Simon D. Platt, CPA, has calculated Dey's average sales prices ("ASP")[2] for the Subject Drugs, aggregating the sales transaction data on a quarterly basis, and net of chargebacks, rebates, and discounts. Mr. Platt has calculated net ASPS for Dey's direct sales, and for Dey's indirect sales. (Henderson Ex. 19, at ¶¶ 12,14.)

Dey's Response: Dey disputes US-SOF No. 72 as unsupported by the evidence cited. For the purposes of this motion, Dey does not dispute that Mr. Platt's calculations are mathematical calculations of what Mr. Platt purports to be average selling prices for various Dey drugs. Mr. Platt testified that he performed a straightforward exercise in arithmetic computation:

> Q. Now, your calculation of average prices is a straightforward exercise in arithmetic computation; right?
>
> A. Yes. Once the net sales amount has been arrived at and the adjustment for shelf cartons and so on and so forth, but yes.
>
> Q. It doesn't require any particular expertise to come up with those numbers?
>
> A. I'm sorry. Which numbers?
>
> Q. The average sales prices. The calculation of average prices once you have the net sales data, it doesn't require any particularized expertise to come up with that; isn't that right?
>
> A. Once you've arrived at the net sales amount being the numerator and the quantities being the denominator, the pure calculation of the average is a straightforward mathematical exercise.
>
> Q. And arriving at the net sales is also a straightforward mathematical exercise once you have the amount billed and the various deductions that you decide to subtract; right?

[2] The term "average sales price" or "ASP" is not intended to refer to the term as used in the Medicare statute, 42 U.S.C. § 1395w-3a(c).

> A. Once you've decided what are the elements that comprise net sales from the data, yes, and the application of accounting principles, yes.

(Reid Decl., Ex. 342, Deposition of Simon Platt, dated 3/18/09 ("3/18/09 Platt Dep."), at 269:9-270:10).

However, Dey does dispute that Mr. Platt's calculations are probative evidence that the average price as calculated by Mr. Platt should have been reported by Dey in the pricing compendia. Mr. Platt clearly and repeatedly testified that: "I wasn't retained to and I have no opinion on what Dey should have reported as its AWP. I think I've said that now a couple of times. That wasn't what I was asked to do, and that's not what I've done, and that's not what I've opined." (Reid Decl., Ex. 342, 3/18/09 Platt Dep. 152:12-16). Dey further disputes the implication that had Dey reported the prices calculated by Mr. Platt, they would have been used by Medicaid or Medicare as a basis of reimbursement. (*See* Defendants' Response to Common SOF Nos. 35, 120).

In addition, Mr. Platt's calculations do not in fact reflect the average "wholesale" price because Mr. Platt did not examine the wholesaler data. Mr. Platt provided the following testimony:

> Q. Now, if the -- if an objective was, in these cases, was to try to determine the average price paid by providers who actually dispense the drugs and then submit claims to Medicaid, to determine what those providers paid to wholesalers for acquiring the drugs that they ultimately dispensed, would you agree that the best data to do that would be the wholesalers' data?
>
> * * *
>
> MS. THOMAS: Objection.
>
> A. I would agree in part. First of all, as we've seen, there are some providers that are direct customers of Dey who are not wholesalers. So presumably they are providing directly, and the prices which they are paying are the prices that Dey sees in its sales transactions. To the extent providers have purchased through a wholesaler and to the extent the

> information that the wholesaler is providing back to Dey on its contract sales does not accurately reflect the price, then I agree that you'd need to fill that hole best in an absolute sense by going to the wholesalers' records. Whether or not Dey could do that, I have no idea, but in principle there could be some elements of the calculation you outline best obtained from the wholesalers' records.

(Reid Decl., Ex. 342, 3/18/09 Platt Dep. 233:22-235:5).

73. Mr. Platt has also compared Dey's average net sales prices to the AWPs and WACs reported by First DataBank and Red Book, and has calculated the "spreads" on Dey's drugs, i.e., the percentage markup over Dey's ASP, aggregating the data annually. These calculations and comparisons show that Dey's AWPs were substantially higher than the prices generally and currently paid in the market for Dey's products. (Henderson Ex. 19, at ¶¶ 12, 14.)

Dey's Response: Dey disputes US-SOF No. 73 as unsupported by the evidence cited. The paragraphs of Mr. Platt's declaration, Henderson Ex. 19, cited by the Government do not support this statement. Furthermore, nowhere in Mr. Platt's declaration, Henderson Ex. 19, does Mr. Platt state that the figures he has calculated are the "prices generally and currently paid in the market for Dey's products." Nowhere does Mr. Platt state that Dey's AWPs were substantially higher than the prices generally and currently paid in the market for Dey's products. Dey further disputes the unsupported implication that prices calculated by Mr. Platt reflect the prices generally and currently paid in the market for Dey's products. As Mr. Platt testified, because the numbers he calculated are in fact averages, some providers are paying more for Dey's drugs than the average and others are paying less. (Reid Decl., Ex. 342, 3/18/09 Platt Dep. 116:3-118:22).

74. The AWPs that Dey caused to be published for Dey's Albuterol Sulfate Unit Dose Solution, 0.083%, 3 ml, products, NDC Nos. 49502-0697-03, 49502-0697-24, 49502-0697-33, 49502-0697-29, 49502-0697-30, 49502-0697-60, and 49502-0697-61 ("Albuterol Sulfate Unit Dose"), were substantially higher than the prices at which Dey sold those products to its indirect customers. (Henderson Ex. 19, Graph A4.) Specifically, the spreads between Dey's ASPs for its indirect sales and the published AWPs ranged from 75.6% in 1992 to 301.8% in 1998, to 1246.1% in 2007. (*Id.*, Summaries A4, A5, A6.)

Dey's Response: Dey disputes the statement in US-SOF No. 74 that "The AWPs that Dey caused to be published" as a legal conclusion unsupported by admissible evidence in violation of Fed. R. Civ. P. 56 and Local Rule 56.1. Dey disputes that the graphs and summaries attached to the declaration of Mr. Platt reflect "the prices at which Dey sold those products to its indirect customers." As Mr. Platt testified, because the numbers he calculated are in fact averages, some providers are paying more for Dey's drugs than the average and others are paying less. (Reid Decl., Ex. 342, 3/18/09 Platt Dep. 116:3-118:22). Dey further states that dollar margins and spreads on generic prescriptions are exaggerated and misleading when presented in percentage terms, and in the case of Dey, are the result of generic price competition. (*See* Dey-SOF No. 62; 6/26/09 Bradford Decl. ¶ 13). Dey incorporates its response to US-SOF No. 72.

75. The AWPs that Dey caused to be published for Dey's Albuterol Sulfate Metered Dose Inhaler, 17g, NDC Nos.49502-0303-17 and 49502-0333-17 ("Albuterol Sulfate MDI"), were substantially higher than the prices at which Dey sold those products to its indirect customers. (Henderson Ex. 19, Graph A1.) Specifically, the spreads between Dey's ASPs for its indirect sales and the published AWPs ranged from 73.6% in the first year of sales, 1995, to over 638% in 2000, and 408.9% in 2003. (Henderson Ex. 19, Summary Al.)

Dey's Response: Dey disputes the statement in US-SOF No. 75 that "The AWPs that Dey caused to be published" as a legal conclusion unsupported by admissible evidence in violation of Fed. R. Civ. P. 56 and Local Rule 56.1. Dey disputes that the graphs and summaries attached to the declaration of Mr. Platt reflect "the prices at which Dey sold those products to its indirect customers." As Mr. Platt testified, because the numbers he calculated are in fact averages, some providers are paying more for Dey's drugs than the average and others are paying less. (Reid Decl., Ex. 342, 3/18/09 Platt Dep. 116:3-118:22). Dey further states that dollar margins and spreads on generic prescriptions are exaggerated and misleading when presented in percentage terms, and in the case of Dey, are the result of generic price competition.

(*See* Dey-SOF No. 62; 6/26/09 Bradford Decl. ¶ 13). Dey incorporates its response to US-SOF No. 72.

76. The AWPs that Dey caused to be published for Dey's Albuterol Sulfate MDI Refill, 17g, NDC Nos. 49502-0303-27 and 49502-0333-27, were substantially higher than the prices at which Dey sold those products to its indirect customers. (Henderson Ex. 19, Graph A2.) Specifically, the spreads between Dey's ASP for its indirect sales and the published AWPs ranged from 356.7% in 1996 to approximately 600% in 2000. (*Id.*, Summary A2.)

Dey's Response: Dey disputes the statement in US-SOF No. 76 that "The AWPs that Dey caused to be published" as a legal conclusion unsupported by admissible evidence in violation of Fed. R. Civ. P. 56 and Local Rule 56.1. Dey disputes that the graphs and summaries attached to the declaration of Mr. Platt reflect "the prices at which Dey sold those products to its indirect customers." As Mr. Platt testified, because the numbers he calculated are in fact averages, some providers are paying more for Dey's drugs than the average and others are paying less. (Reid Decl., Ex. 342, 3/18/09 Platt Dep.116:3-118:22). Dey further states that dollar margins and spreads on generic prescriptions are exaggerated and misleading when presented in percentage terms, and in the case of Dey, are the result of generic price competition. (*See* Dey-SOF No. 62; 6/26/09 Bradford Decl. ¶ 13). Dey incorporates its response to US-SOF No. 72.

77. The AWPs that Dey caused to be published for Dey's Albuterol Sulfate Multi-Dose Solution, .5%, 20 ml, NDC Nos. 49502-0196-20 and 49502-0105-01, were substantially higher than the prices at which Dey sold those products to its indirect customers. (Henderson Ex. 19, Graph A3.) Specifically, the spreads between Dey's ASP for its indirect sales and the published AWPs ranged from 160.5% in 1996 to 364.8% in 2003. (*Id.*, Summary A3.)

Dey's Response: Dey disputes the statement in US-SOF No. 77 that "The AWPs that Dey caused to be published" as a legal conclusion unsupported by admissible evidence in violation of Fed. R. Civ. P. 56 and Local Rule 56.1. Dey disputes that the graphs and summaries attached to the declaration of Mr. Platt reflect "the prices at which Dey sold those products to its

indirect customers." As Mr. Platt testified, because the numbers he calculated are in fact averages, some providers are paying more for Dey's drugs than the average and others are paying less. (Reid Decl., Ex. 342, 3/18/09 Platt Dep. 116:3-118:22). Dey further states that dollar margins and spreads on generic prescriptions are exaggerated and misleading when presented in percentage terms, and in the case of Dey, are the result of generic price competition. (*See* Dey-SOF No. 62; 6/26/09 Bradford Decl. ¶ 13). Dey incorporates its response to US-SOF No. 72.

78. The AWPs that Dey caused to be published for Dey's Cromolyn Sodium Unit Dose Solution, 20 mg, 2 ml, NDC Nos. 49502-0689-12, 49502-0689-02, and 49502-0689-61, were substantially higher than the prices at which Dey sold those products to its indirect customers. (Henderson Ex. 19, Graphs A7 & A8.) Specifically, the spreads between Dey's ASP for its indirect sales and the published AWPs ranged from 42.1% in 1994 to 424.7% in 2004. (*Id.*, Summaries A7 & A8.)

Dey's Response: Dey disputes the statement in US-SOF No. 78 that "The AWPs that Dey caused to be published" as a legal conclusion unsupported by admissible evidence in violation of Fed. R. Civ. P. 56 and Local Rule 56.1. Dey disputes that the graphs and summaries attached to the declaration of Mr. Platt reflect "the prices at which Dey sold those products to its indirect customers." As Mr. Platt testified, because the numbers he calculated are in fact averages, some providers are paying more for Dey's drugs than the average and others are paying less. (Reid Decl., Ex. 342, 3/18/09 Platt Dep. 116:3-118:22). Dey further states that dollar margins and spreads on generic prescriptions are exaggerated and misleading when presented in percentage terms, and in the case of Dey, are the result of generic price competition. (*See* Dey-SOF No. 62; 6/26/09 Bradford Decl. ¶ 13). Dey incorporates its response to US-SOF No. 72.

79. The AWPs that Dey caused to be published for Dey's Ipratropium Bromide Unit Dose Solution, .02%, 2.5 ml, NDC Nos. 49502-0685-03, 49502-0685-24, 49502-0685-26 49502-0685-33, 49502-0685-29, 49502-0685-31, 49502-0685-30, 49502-0685-60, 49502-068561, and 49502-0685-62, were substantially higher than the

prices at which Dey sold those products to its indirect customers. (Henderson Ex. 19, Graphs A9, A10, A11.) Specifically, the spreads between Dey's ASP for its indirect sales and the published AWPs ranged from 105.6% in 1997 to 1699.8% in 2003. (*Id.*, Summaries A9, A10, A11.)

Dey's Response: Dey disputes the statement in US-SOF No. 79 that "The AWPs that Dey caused to be published" as a legal conclusion unsupported by admissible evidence in violation of Fed. R. Civ. P. 56 and Local Rule 56.1. Dey disputes that the graphs and summaries attached to the declaration of Mr. Platt reflect "the prices at which Dey sold those products to its indirect customers." As Mr. Platt testified, because the numbers he calculated are in fact averages, some providers are paying more for Dey's drugs than the average and others are paying less. (Reid Decl., Ex. 342, 3/18/09 Platt Dep. 116:3-118:22). Dey further states that dollar margins and spreads on generic prescriptions are exaggerated and misleading when presented in percentage terms, and in the case of Dey, are the result of generic price competition. (*See* Dey-SOF No. 62; 6/26/09 Bradford Decl. ¶ 13). Dey incorporates its response to US-SOF No. 72.

80. The WACs that Dey caused FDB to publish from June 1, 1995, to December 1, 1998, were substantially higher than the prices generally and currently paid by wholesalers who purchased the drugs from Dey. (Henderson Ex. 19, Graphs A12, A13.) Specifically, the spreads between Dey 's ASP for its direct sales to the wholesaler class of trade and the published WACs ranged from 150% in the second half of 1995 to 237% in 1997 Q4. (*Id.*, Summaries A12, A13.)

Dey's Response: Dey disputes US-SOF No. 80. Dey incorporates its responses to US-SOF Nos. 67-79 as if fully set forth herein. Dey disputes that it is responsible for First Databank's failure to correct the WAC prices for Dey's albuterol unit dose on December 4, 1995 when Dey submitted corrected prices. (*See* Dey's Responses to US-SOF Nos. 67-71).

Dey also disputes that the graphs and summaries attached to the declaration of Mr. Platt reflect "the prices generally and currently paid by wholesalers who purchased the drugs from Dey." As Mr. Platt testified, because the numbers he calculated are in fact averages, some

providers are paying more for Dey's drugs than the average and others are paying less. (Reid Decl., Ex. 342, 3/18/09 Platt Dep. 116:3-118:22). Dey further states that dollar margins and spreads on generic prescriptions are exaggerated and misleading when presented in percentage terms, and in the case of Dey, are the result of generic price competition. (*See* Dey-SOF No. 62; 6/26/09 Bradford Decl. ¶ 13).

81. Before the launch of Dey's Albuterol Sulfate Unit Dose product, NDC 49502-697-03, Dey's Vice President of Sales and Marketing, Robert Mozak, sent a memorandum dated February 24, 1992, to Pamela Marrs, Charles Rice, and Jean-Pierre Termier, setting forth the proposed pricing for Dey's new product, Albuterol Sulfate Inhalation Solution, in the unit dose form, NDC 49502-697-03. Pamela Marrs was and is the Chief Financial Officer; Charles Rice was the Chief Operating Officer and became President and CEO in the summer of 1992 (Henderson Ex. 34, at 341); and Jean-Pierre Termier was the President at the time. The memorandum includes an attachment which described Dey's pricing strategy for the drug. The attachment shows a proposed AWP for the Dey product of $32.30. In the attachment, in bullet-points, one of Dey's three "pricing objectives" was to:

> PROVIDE AN INCENTIVE TO RETAIL AND CHAIN PHARMACIES TO PURCHASE DEY'S ALBUTEROL UNIT DOSE BY INCREASING THE SPREAD ON MEDICARE/MEDICAID REIMBURSEMENTS.

(Henderson Ex. 35.) There follows a description of Dey's "pricing strategies," with the first two bullets stating:

> 1) INCREASE THE SPREAD TO RETAIL/HOMECARE ACCOUNTS BY LOWERING ACQUISITION COST MORE THAN AWP
>
> 2) PHARMACY CHAIN BID RANGE: $23.95 - $26.50 (AVG. $25.95) WILL INCREASE SPREAD FOR RETAIL AND PROVIDE DEY WITH HIGHEST PROFIT

Dey's Response: Dey disputes US-SOF No. 81 because it misquotes and mischaracterizes Henderson Exhibit 35, which is a memorandum titled "Albuterol Pricing Strategies," dated February 24, 1992. Dey refers to the entirety of Exhibit 35 as the best evidence of its contents. Dey further disputes US-SOF No. 81 because it provides an incomplete, and therefore misleading, description of the relevant facts.

The bullet-point referred to by Plaintiffs as one of three "pricing objectives" actually provides:

> TO PROVIDE INCENTIVE TO RETAIL/CHAIN PROVIDERS TO USE DEY'S ALBUTEROL UD BY INCREASING THE SPREAD ON MEDICARE/MEDICAID REIMBURSEMENTS.

(*See* Henderson Ex. 35, at DL-TX-0090852 (corrected text underlined)).

Dey's witnesses testified that this bullet point simply refers to a one-time pricing strategy that is used at launch when a first-to-market generic enters the market and must compete against the existing brand. In the early 1990s, when Dey launched its albuterol product, most Medicaid programs did not have mandatory generic substitution programs in place. (Reid Decl., Ex. 343, Deposition of Charles Rice, dated 3/24/03, ("3/24/03 Rice Dep."), at 607:8-23; 6/26/09 Bradford Decl., ¶ 13). Therefore, when launching a first-to-market generic, like Dey's albuterol unit dose, a manufacturer, like Dey, needed to create a financial incentive to encourage a pharmacist to dispense the first-to-market generic instead of the more expensive brand product. (Reid Decl., Ex. 344, Deposition of Robert F. Mozak, dated 3/13/03 ("3/13/03 Mozak Dep."), at 727:8-728:20; Ex. 300, 5/15/08 Dey Dep. 226:7-227:1).

As Dey's corporate designee, Ms. Marrs, testified:

> Q. And, in fact, that same strategy [referring to bullet point above] was subsequently used by Dey's sales force to incentivize customers to purchase Dey's products based upon the greater spread between acquisition cost and Medicaid reimbursement for the purchase of Dey's product versus a competitor's generic product; isn't that correct?
>
> Mr. Doyle: Objection as to form.
>
> The witness: I'm not sure I followed that.
>
> Q. Sure. In fact, subsequent to this it became an accepted practice within Dey's sales force to incentivize customers to purchase Dey's generic products by marketing the larger spread available to providers who purchased Dey's products than the spread available to them from the purchase of a competitor's product?

> Mr. Doyle: Objection as to form.
>
> The witness: You say "practice" as if it's a – it was a pervasive and primary effort of a sales force, and that's not my impression from looking at the documents.
>
> You know, what I've seen is we've produced millions of documents, and there are a handful of documents that refer to the spread.
>
> They tend to be focused more on the launch of Albuterol and Cromolyn, not on Ipratropium that I recall.
>
> I've seen something called "the reimbursement spreadsheet" where we were seeking to convert customers from multi-dose to unit use Albuterol which made reference to the calculated spread on both products.
>
> What I haven't seen are, you know, hundreds of documents that refer to this.
>
> So I – you know, from other testimony given and from talking to internal people it's my impression that, while this was a factor, it wasn't the primary factor. It wasn't a significant part of the ongoing effort.
>
> It was used more at – at launch to set the price, and – you know, I think, if it was pervasive, there probably would be more than a handful of documents that have been located.

(Reid Decl., Ex. 300, 5/15/08 Dey Dep. 227:3-229:6).

As Mr. Rice testified, in order for generics to have any uptake in the market, there had to be an increase in the spread compared to the brand that was currently on the market. (Reid Decl., Ex. 343, 3/24/03 Rice Dep. 589:15-21). The generic incentive is to increase the spread over that of the brand in order to get providers to switch from the brand to the generic in the absence of mandatory generic substitution programs which was the norm in 1992 when albuterol unit dose was launched. (Reid Decl., Ex. 343, 3/24/03 Rice Dep. 607:8-21; 6/26/09 Bradford Decl., ¶ 13).

Ms. Marrs provided similar testimony:

> Q. So in this instance, in February 1992, Mr. Mozak proposed a pricing strategy of providing incentive to customers to purchase Dey's generic

> product by increasing the spread between a provider's acquisition cost and a provider's reimbursement by Medicare and Medicaid systems?
>
> A. What I understand, having looked at some other depositions, is that it was Bob's intent to make sure that the retailer was incentivized to stock the generic instead of the brand, and the way to do that was to reduce the selling price down so that the difference between the reimbursement rate and what the customer purchased it at was higher than what the brand comparable differential would be.

(Reid Decl., Ex. 300, 5/15/08 Dey Dep. 226:7-227:1).

Mr. Mozak testified that Exhibit 35 reflects a situation in which Dey establishes launch pricing and is not an example of "marketing the spread." (Reid Decl., Ex. 344, 3/13/03 Mozak Dep. 730:1-3). Mr. Mozak testified that it was Dey's "intention to discount the product from the branded product so that we would then have a lower reimbursement, we would establish a lower WAC, we would establish a lower AWP. Pharmacists would benefit, patients would benefit, and certainly the State would benefit as well." (Reid Decl., Ex. 344, 3/13/03 Mozak Dep. 727:13-18). According to Mozak, the spread referred to in Exhibit 35 is the difference in the brand price and the generic price. This spread will incentivize providers to switch from the brand to Dey's generic, thus saving money for Medicaid and Medicare programs because of the generic's lower pricing. (Reid Decl., Ex. 344, 3/13/03 Mozak Dep. 740:10-18).

According to Mozak, the increase in spread referenced in the bullet point from Exhibit 35 results from pharmacies being able to purchase generics at a lower price than branded products. There is not necessarily an increased spread with respect to reimbursement by Medicaid or Medicare. When the product is first launched, it sells at around WAC – sometimes higher than WAC. The incentive for pharmacists to purchase the generic product is that the acquisition cost is lower and competition forces contract prices for generics to continue to decrease. (Reid Decl., Ex. 344, 3/13/03 Mozak Dep. 737:4-739:18, 741:13-742:5).

Ms. Burnham Selenati testified that the introduction of Dey's generic albuterol unit dose product caused the government to reimburse less for albuterol because Dey's product was priced lower than the brand:

> Q. And the Dey AWP you knew was lower than the brand that existed, right?
>
> A. That's right.
>
> Q. So any entity that reimbursed on the basis of AWP would automatically be paying less on reimbursement for the Dey product than the existing brand, correct?
>
> A. That's correct.
>
> Q. Okay, So once Dey came into the market and launched its albuterol, every government agency that reimbursed on AWP was saving money because of the introduction of Dey, right?
>
> A. They were paying less, yes.

(Reid Decl., Ex. 325, 5/5/05 Burnham Selenati Dep. 305:11-25).

Ms. Burnham Selenati also testified that she believed that Dey's albuterol product was better for patients, better for reimbursing entities, and better for the providers. (Reid Decl., Ex. 325, 5/5/05 Burnham Selenati Dep. 311:24-313:3). Mr. Mozak also testified that Exhibit 35 reflects a "win-win" situation for both Dey and the government. Dey won by providers switching from the brand to Dey's generic albuterol and the government won because they were reimbursing on a lower WAC and AWP than the brand. (Reid Decl., Ex. 344, 3/13/03 Mozak Dep. 725:1-726:4).

Moreover, the language in Exhibit 35 concerning "increasing the spread" does not refer to a situation in which Dey would be intentionally manipulating its reported prices. Dey did not manipulate its AWP upwards to create an artificial spread. (Reid Decl., Ex. 343, 3/24/03 Rice Dep. 602:6-603:6). Rather, the only way that Dey's spread for the Subject Drugs was increased

over time was through declining contract prices. (6/26/09 Stiroh Decl., Figures A-K). This decline in contract prices and subsequent increase in spread was reflected in Dey's reported AMP and WAC and publicly available to the government. (*See* Dey-SOF Nos. 97-103).

The spread is something the Government created, not Dey. Mr. Tipton testified:

> Q. And this whole existence of spread, it's not something that Dey or indeed any other drug company came up with, right?
>
> A. Correct.
>
> Q. Who created the spread?
>
> A. The, you know, the spread, I believe, was created by a government agency for reimbursement way back when. I don't know anything beyond that.

(Reid Decl., Ex. 345, Deposition of Bruce Tipton, dated 3/21/06 ("3/21/06 Tipton Dep."), at 282:2-11).

Moreover, Dey is powerless to change the system on its own:

> I'm saying that as a practical matter, the system – I mean there's all kinds of testimony and documentation that this is a flawed system. I'm sure that that's – you know, those documents you've seen.
>
> What I'm saying is that the way the system was set up, it really didn't allow for that. And our position has always been, fine, lower AWP, but do it for everyone. Treat everyone the same, because otherwise, the companies that – if you lowered AWP for one company and not the other who's selling the same generic drug, then – then the pharmacists won't buy your drug.
>
> So the system is what really needs to be fixed. There have been recent actions to try to take care of that.

(Reid Decl., Ex. 305, 7/10/08 Dey Dep. 367:1-17).

82. Also before the launch of Dey's albuterol sulfate unit dose, NDC 49502-0697-03, Dey's Vice President of Sales and Marketing, Robert Mozak, asked Dey Marketing Manager Helen Burnham (later Helen Selenati) to contact First DataBank ("FDB") and find out what would be the highest AWP that Dey could report and still ensure that the drug would be classified by FDB as a generic. Ms. Burnham contacted Ed Edelstein at FDB who, according to Ms. Burnham, told her that, in order to ensure its

> status as a generic, the AWP had to be at least ten percent below the AWP of the brand version. (Henderson Ex. 36, at 46-47.)

Dey's Response: Dey disputes US-SOF No. 82. There is an issue of material fact concerning Ms. Burnham Selenati's call to First DataBank and any instructions Mr. Mozak may have given her. Mr. Mozak testified that First DataBank advised Dey to set the AWP at approximately ten percent below the branded product and the WAC price somewhere between 15 to 25 percent below the AWP price. (Reid Decl., Ex. 344, 3/13/03 Mozak Dep. 731:12-24). Mozak did not testify that he told Ms. Burnham Selenati to find out the "highest AWP that Dey could report and still ensure that the drug would be classified by FDB as a generic."

Moreover, Dey followed industry practice when it set its AWP at approximately 10% of the AWP for the therapeutically equivalent brand product's AWP. (Reid Decl., Ex. 305, 7/10/08 Dey Dep. 460:2-462:10). In order to compete in the generic marketplace, a manufacturer needs a level playing field on which to compete, which is accomplished by having an AWP that is approximately 10% below the brand AWP and in line with generic competitors' AWPs for the same product. (Reid Decl., Ex. 305, 7/10/08 Dey Dep. 469:12-15; Ex. 346, Deposition of Pamela Marrs, dated 10/2/08 ("10/2/08 Dey Dep."), at 773:4-21; Ex. 347, Deposition of Todd Galles, dated 2/28/06 ("2/28/06 Galles Dep."), at 43:18-44:13).

As Dey's experience shows, the failure to follow the industry practice of setting AWP for a generic at 10% off the brand forced Dey out of business with respect to its ipratropium nasal spray product. As Ms. Marrs testified:

> We did have a product that we tried to launch and it was in the middle of when people were trying to figure out what all this litigation was about. It was a nasal spray product. We launched. We set a very low WAC and AWP, much lower than our competitors, and we had to discontinue the product. No one would buy it.
>
> So it pretty much put us out of business on that product.

(Reid Decl., Ex. 305, 7/10/08 Dey Dep. 368:6-369:1).

Moreover, in April 2003, Dey almost lost its entire generic business when First DataBank and Medispan unilaterally reduced Dey's AWP without reducing the AWPs of Dey's competitors. (Reid Decl., Ex. 348, ¶¶ 7-12; Ex. 349, ¶¶ 3-6; Ex. 350, ¶¶ 3-8). During the week of April 7, 2003, First DataBank and Medispan began to list AWPs for Dey's albuterol, ipratropium, and cromolyn products that bore no relationship to Dey's suggested AWPs or to any AWP previously listed for Dey's products. (Reid Decl., Ex. 348, ¶ 7). First DataBank and Medispan did not change the AWPs reported for products of Dey competitors, however. Dey only became aware of this change on April 10, 2003 when it received a series of customer complaints regarding the AWPs published by First DataBank and Medispan. (Reid Decl., Ex. 348, ¶¶ 6-7, 14; Ex. 350, ¶¶ 4-6; Ex. 349, ¶¶ 3-6).

The impact of First DataBank and Medi-Span's actions became rapidly apparent. Within one day, numerous customers contacted Dey. (Reid Decl., Ex. 348, ¶¶ 6-7, 14; Ex. 350, ¶¶ 4-6, Ex. 349, ¶¶ 3-6). These customers uniformly stated that, due to the drastically changed manner in which AWPs for Dey products were so suddenly changed, reimbursements for Dey products had been radically reduced and that they would be forced to switch to Dey competitors. (Reid Ex. 348, ¶¶ 6-7, 14; Ex. 350, ¶¶ 4-6, Ex. 349, ¶¶ 3-6).

Days after the first customer complaints began pouring in, Dey made an application for a temporary restraining order to restore the status quo and to reinstate the AWPs that had been in place prior to the change. Dey's application was granted and the matter was later settled. Had the AWPs not been reinstated, Dey would have been forced to almost immediately curtail its manufacturing operations in Napa in anticipation of a mass customer defection, and most likely would have ceased to be a viable company. (Reid Decl., Ex. 353, ¶ 9).

As Ms. Marrs testified:

> Q. And in fact, when First DataBank did not publish the AWP that Dey had reported, Dey took action to correct the situation?
>
> A. Well, the way we learned of the fact that they hadn't published –
>
> Q. I'm not asking you how you learned.
>
> A. Let me finish. Let me finish. We did nothing to control that situation. We only became aware of it when our customers called us threatening to not purchase our product anymore because they had been notified by First DataBank of this price that we knew nothing about, and we were faced with the situation where if we didn't take some action, those customers all would have gone away and the plant in Napa would have closed.

(Reid Decl., Ex. 305, 7/10/08 Dey Dep. 468:3-18).

83. Ms. Burnham prepared a marketing plan for the albuterol unit dose product, dated February 1992. (Henderson Ex. 37, at 281-282 & Dep. Ex. 51 (selected pages).) The marketing plan contained a "pricing strategies" discussion that included language identical to that quoted in paragraph 81, above. (*Id.*) The marketing plan also stated that "Selling price will average $15.00 in first 12 months." (*Id.*)

Dey's Response: Dey disputes US-SOF No. 83. Dey incorporates its responses to US-SOF Nos. 81-82 as if fully set forth herein.

84. Dey reported an AWP of $32.25 to FDB, which was about ten percent below that of the brand. (Henderson Ex. 19, Summary A4.) Dey's average selling price for most of 1992 was about $17.90. (*Id.*)

Dey's Response: Dey disputes US-SOF because it contains an incomplete description of the relevant facts and is therefore misleading. Dey also disputes US-SOF No. 84 as unsupported by the evidence cited with respect to the average selling prices it set forth. Dey incorporates its response to US-SOF No. 72 as if set forth fully herein. For purposes of this motion, Dey does not dispute that Mr. Platt's calculations are mathematical calculations of what Mr. Platt purports to be average selling prices for various Dey drugs. (Reid Decl., Ex. 342, 3/18/09 Platt Dep. 269:9-270:10). However, Dey does dispute that Mr. Platt's calculations are probative evidence that the average prices as calculated by Mr. Platt should have been reported by Dey in the pricing

compendia. (Reid Decl., Ex. 342, 3/18/09 Platt Dep. 152:12-16). Dey further disputes the implication that had Dey reported the prices calculated by Mr. Platt, they would have been used by Medicaid or Medicare as a basis for reimbursement. (*See* Response to DOJ Common SOF, ¶¶ 35, 120).

Dey does not dispute that it reported an AWP of $32.25 to First DataBank which was approximately 10 percent below the brand's AWP, but states that it also provided a WAC of $24.95 to First DataBank at the same time it provided the AWP. (6/26/09 Stiroh Decl., Figures A-K). Dey reported reductions to the WAC for albuterol unit dose on a regular basis. (6/26/09 Stiroh Decl., Figures A-K; Dey's Response to US-SOF Nos. 67-71). The WAC, and all reductions to WAC, was as available to state and federal governments as was the AWP through First DataBank and other price reporting services. (6/26/09 Stiroh Decl., Figures A-K).

85. For reasons that are unclear, beginning the third quarter of 1994 Dey dropped its AWP to $30.25. Thereafter Dey never changed it. (Henderson Ex. 19, Summary A4.)

Dey's Response: Dey disputes US-SOF No. 85. Dey does not dispute that the AWP for its albuterol unit dose product changed to $30.25 sometime in 1993 or 1994. Dey does not dispute that it has not changed the AWP for its albuterol unit dose product from $30.25 nor does Dey dispute that it did not thereafter change the AWP for its albuterol unit dose product.

Dey disputes the remainder of US-SOF No. 85 because it presents an incomplete and selective description of the facts, and is therefore misleading. First, CMS set a FUL for albuterol unit dose in October 1997. (Reid Decl., Ex. 354, at A-1). Thereafter, no state Medicaid office should have used Dey's AWP to reimburse Medicaid claims while the FUL remained in effect. Second, Ms. Marrs testified that Dey's practice of not changing the AWPs for Dey's generic products was in accordance with industry practice:

> Q. And has it historically been typically the case that Dey does not change the AWP once it's been set at the time of launch of a new product?

> A. For generic products, that's correct. It's again, my understanding that that's an industry practice, that AWP is not changed.

(Reid Decl., Ex. 300, 5/15/08 Dey Dep. 132:5-12; *see also* Reid Decl., Ex. 305, 7/10/08 Dey Dep. 502:1-503:8; Ex. 346, 10/2/08 Dey Dep. 736:21-737:20; Dey's Response to US-SOF No. 82).

86. Sales for Dey's Albuterol unit dose product were strong in 1992. By January 1993, Dey had doubled in size as a company due to its Albuterol product, adding many new sales personnel. (Henderson Ex. 38.)

Dey's Response: Dey disputes US-SOF No. 86 because it is vague, irrelevant, and is based on hearsay, and thus is unsupported by admissible evidence in violation of Fed. R. Civ. P. 56 and Local Rule 56.1. Moreover, US-SOF No. 86 incorrectly cites Mr. Ellis's memo.

Mr. Ellis's memo does not provide that Dey "add[ed] many new sales personnel." Rather, all Mr. Ellis's memo states is that: "When I first arrived, there were only eight outside reps and only four telesales reps. Now there are twelve outside reps and a potential of five new positions to be filled. Internally, telesales has doubled to reach a total of eight reps who are constantly busy." (*See* Henderson Ex. 38, at DL-60046).

87. In approximately July 1993, Dey began facing competition from another generic manufacturer for the albuterol sulfate unit dose product. (Henderson Ex. 39.) Dey reduced its prices to meet the competition. (*Id.*) Dey did not reduce its AWPs. (Henderson Ex. 19, Summary A4.)

Dey's Response: Dey disputes US-SOF No. 87 because it provides an incomplete and therefore misleading description of the relevant facts. Dey incorporates its objections to Henderson Exhibit 19 as set forth in Dey's response to US-SOF No. 72 above.

Dey does not dispute that it began facing generic competition for its albuterol unit dose product in approximately mid-1993 and that Dey reduced its contract and WAC price for albuterol unit dose to meet the competition in approximately August 1993. (6/26/09 Stiroh Decl., Figures A-K).

Dey does not dispute that it did not reduce its AWPs for albuterol unit dose, with the exception of one reduction in or about 1993 or 1994. Dey further states that its practice of leaving its AWP flat over time was in accord with industry practice and Dey would likely have been forced out of business had it not followed industry practice. (*See* Dey's Responses to US-SOF Nos. 82-83).

Dey also states that as contract prices for the Subject Drugs, including albuterol unit dose, declined over time, Dey reduced the WAC for those drugs. (*See* Dey-SOF No. 74). As Debra Bronstein, Dey's marketing director from 1996 to 2000, testified:

> Q. [D]o you consider WAC to be a fictitious price or do you consider WAC to be a meaningful price from the standpoint of a manufacturer?
>
> A. It's a jumping off point. It's a meaningful price….an anchor is probably what I would call it.

(Reid Decl., Ex. 335, Bronstein Dep. 263:21-264:2).

Dey regularly updated its WACs in a manner that directly reflected underlying pricing activity. (*See* Dey-SOF No. 75). Throughout the relevant time period, Dey reported WACs for the Subject Drugs, including albuterol unit dose, to pricing compendia such as First DataBank, RedBook, and Medispan. (*See* Dey-SOF No. 76). Moreover, Dey notified price reporting services and state Medicaid offices as soon as the WAC was lowered. (*See* Dey-SOF No. 77). In addition, Dey also reported AMP to CMS. (*See* Dey-SOF No. 90). As seen in Figures A through K to the Stiroh Declaration, Dey's AMP tracks slightly below Dey's published WAC for prices through 2004. (*See* Dey-SOF No. 105).

88. In the years that followed, increasing competition caused Dey to lower its sales prices. Dey did not lower its AWPs. (Henderson Ex. 19, Graphs A4, A5, A6.)

Dey's Response: Dey disputes US-SOF No. 88 because it does not relate specifically to the drugs at issue and because it is immaterial to the issues before the Court. Dey incorporates

its responses to US-SOF Nos. 82-87 and its objections to Mr. Platt's calculations contained in Henderson Exhibit 19 as if fully set forth herein.

Dey further states that its profits on its generic products decreased as prices eroded in the marketplace. (Dey-SOF No. 58; Reid Decl., Ex. 325, 5/5/05 Burnham Selenati Dep. 344:7-14). Dey did not receive any proceeds from the spread. Dey did not profit from the increasing spread on its products. In fact, although Dey continues to manufacture and sell albuterol unit dose, it is no longer profitable. (*See* Dey-SOF No. 19). Dey stopped manufacturing cromolyn in February 2008 as it was unable to sustain a profit on sales. (*See* Dey-SOF No. 32). Dey continues to sell ipratropium at a close to break even profit level. (*See* Dey-SOF No. 38).

89. In 1993 Dey Marketing Assistant (and later Product Manager) Robert Ellis was assigned to collect information about the reimbursement methodologies of state Medicaid programs and the Medicare program, as they related to Dey's drugs. (Henderson Ex. 40, at 12-17.) He and Dey employee Carrie Jackson collected and created an extensive database of information about state Medicaid reimbursement methodologies and Medicare reimbursement information. He called the state agencies and recorded what their reimbursement structures were and developed a database. (Henderson Ex. 40, at 13; Henderson Ex. 41, at 109-112, and Dep. Ex. 880; Henderson Ex. 42.)

Dey's Response: Dey disputes US-SOF No. 89 because it mischaracterizes the testimony of Mr. Ellis and Ms. Jackson and the testimony cited to does not support the purported facts set forth in US-SOF No. 89. Mr. Ellis did not testify that he created an "extensive database of information" about state reimbursement methodologies. In fact, he testified that he "just put together an Excel spreadsheet." (Reid Decl., Ex. 330, Ellis Dep. 13:18-23). Ellis further testified that the spreadsheet was not generally accessible to others in the Dey organization: "It was just on my computer. I don't think we – I was tied into any – any local network at the time." (Reid Decl., Ex. 330, Ellis Dep. 14:3-10). Dey further disputes US-SOF No. 89 because it mischaracterizes the testimony of Carrie Jean Jackson. Ms. Jackson did not testify that she created an extensive database of information about state Medicaid and Medicare reimbursement

methodologies. Ms. Jackson did not testify that she created any database at all. In fact, she explained that she merely assembled into one document the information she received from individual states regarding their Medicare reimbursement formulas. (Reid Decl., Ex. 355, Deposition of Carrie Jackson, dated 4/18/03 ("Jackson Dep."), at 109:25-110:7). Nor did Ms. Jackson testify that she called state agencies and recorded what their reimbursement structures were. She testified that she sent a form to individual states to be filled out and upon receiving a state's response, she entered the information into her report. (Reid Decl., Ex. 355, Jackson Dep. 110:4-25). In her letter to Martha McNeill dated August 31, 1993, cited by Plaintiffs in US-SOF No. 89, Ms. Jackson explained why Dey gathered such information:

> Many of our customers are Medicaid providers and request reimbursement information when making a purchasing decision. In order to provide them with the best possible service, we periodically request this information from each Medicaid carrier.

(Reid Decl., Ex. 355, Jackson Dep. 18:7-19:23; Ex. 356).

Mr. Mozak testified that the reason for collecting the information in 1993 regarding reimbursement under the Medicare and Medicaid programs was because customers had asked questions regarding whether Dey's drugs were in the formulary and what codes were used for reimbursement. (Reid Decl., Ex. 321, 4/30/02 Mozak Dep 315:2-18). Mr. Mozak testified that the information was not collected for the purpose of informing customers how much they would receive in reimbursement. (Reid Decl., Ex. 321, 4/30/02 Mozak Dep. 315:2-18). In any event, it is not improper for a pharmaceutical company to be aware of the Medicaid reimbursement for its products. As Ms. Burnham Selenati testified, knowledge of Medicaid reimbursement was "essential" to running the business:

> Q. And as a logical matter, you would expect that a pharmaceutical company couldn't really run its business without being aware of how Medicaid reimbursed on some basis, right?

A. No. It was something that was essential to running your business.

(Reid Decl., Ex. 325, 5/5/05 Burnham Selenati Dep. 321:8-13).

Dey further disputes US-SOF No. 89 because it does not relate specifically to the drugs at issue and is immaterial to the issues before the Court.

90. The information on Medicare and Medicaid reimbursement was distributed to Dey's sales force. (*Id.* at 110:23-112:5.)

Dey's Response: Dey disputes US-SOF No. 90. Dey incorporates its objections and response set forth in response to US-SOF No. 89. Dey further disputes US-SOF No. 90 because it mischaracterizes the testimony of Carrie Jean Jackson. Ms. Jackson did not testify that the information she gathered on Medicare and Medicaid reimbursement was "distributed to Dey's sales force." In fact, she merely confirmed that in looking at the distribution list it included, among other employees, certain members of Dey's sales staff. (Reid Decl., Ex. 355, Jackson Dep. 111:11-112:5). In fact, Ms. Jackson testified that she did not know which personnel, if any, would receive the information:

> Q. As you sit here today do you have any understanding as to why you were being asked to do this?
>
> A. Just to update if there were any dollar changes or procedure changes at the individual states. I didn't -- at that point I did not know what distribution would be with this information.

(Reid Decl., Ex. 355, Jackson Dep. 24:23-25:4).

Dey further disputes US-SOF No. 90 because it does not relate specifically to the drugs at issue and is immaterial to the issues before the Court.

91. In later years Dey from time to time acquired information concerning reimbursement practices of State Medicaid programs and Medicare Part B. (Henderson Exs. 43, 44,45).

Dey's Response: Dey disputes US-SOF No. 91. Dey incorporates its objections and responses set forth in response to US-SOF Nos. 89-90 above. The memoranda sent by Ms.

Jackson on August 12, 1993 and February 2, 1994 regarding reimbursement practices of state Medicaid and Medicare programs were the only two reports of their kind. (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 186:6-187:8; Ex. 321, 4/30/02 Mozak Dep. 313:12-314:2). In fact, Ms. Jackson explained that after her February 1994 report it was specifically decided that such information would not be prepared on any systematic basis. She testified:

> Q. And does this -- does looking at this document help you to remember how you gathered the information?
>
> A. What it does bring to mind, as I remember, there was a period of months there from August '93 to February of '94 where they had wanted this report periodically, more frequent than six months here, and the focus -- I was put on other things, you know, with conventions and that type of thing, so I was unable to get to it and I remember there was a length of time where Helen had asked me, "Okay. Carrie, can you update this?" How I gathered the information, there again, I don't remember.
>
> Q. Okay.
>
> A. So... I remember it was a lot of work and she said, "Well, we are going to do it on an as-needed basis from now on."

(Reid Decl., Ex. 355, Jackson Dep. 24:6-22). Robert Mozak, Executive Vice President of Sales and Marketing for Dey, L.P., testified that Ms. Jackson's reports were the only two ever compiled. He testified as follows:

> Q. Do these Exhibits 230 and 231 refresh your recollection as to whether or not there's any information within your department relating to Medicare reimbursement?
>
> A. Well, obviously these are related to Medicare reimbursement.
>
> Q. Okay. And you indicated these reports -- you recall seeing them many years ago, correct?
>
> A. Yes.
>
> Q. Exhibit 231 is dated 2 February 1994. Do you see that?
>
> A. Yes.

> Q. When was the last time you actually saw a report similar to the ones that appear here in front of you here now?
>
> A. I believe that was the last report, the one in 1994.
>
> Q. Did -- who ordered the discontinuance of the preparation of these reports?
>
> A. I don't know who ordered the discontinuation. I think it was done by Carrie Jackson either on her own volition or through somebody else's request in the department, and it was compiled these two times. I don't believe there are any other additional reports, at least to the best of my knowledge, beyond that date of 1994.

(Reid Decl., Ex. 321, 4/30/02 Mozak Dep. 313:2-314:2). Pamela Marrs, Dey's 30(b)(6) designee, likewise testified that she had not seen documents other than Carrie Jackson's reports regarding state-by-state reimbursement methodology. Ms. Marrs provided the following testimony:

> Q. Rather, my question was whether Dey kept track of changes to the Medicare or Medicaid programs.
>
> MR. DOYLE: Objection as to form.
>
> THE WITNESS: Program --
>
> BY MR. AZORSKY:
>
> Q. Not necessarily on a weekly or monthly regimented basis, but periodically the sales force and the Marketing Department were aware of how their drugs were being reimbursed by the different Medicaid agencies around the country.
>
> MR. DOYLE: Objection as to form.
>
> THE WITNESS: What I have seen that was provided to the Sales Reps from corporate was an AWP price list. I don't know if it was called "price list," but a list of AWPs that was -- that was given to the Sales Rep just for their information in case customers asked. What I'm not aware of, other than having seen the Carrie Jackson memo -- I don't recall seeing documents that talked about reimbursement in terms of the formula by state. It was more just a general AWP worksheet for reference.

(Reid Decl., Ex. 300, 5/15/08 Dey Dep.186:6-187:8).

Dey further disputes US-SOF No. 91 because it does not relate specifically to the drugs at issue and is immaterial to the issues before the Court.

92. Robert Mozak, the former head of Sales and Marketing, knew that Medicaid authorities paid based on prices reported to FDB or Medispan or Red Book. (Henderson Ex. 46, at 492.)

Dey's Response: Dey disputes US-SOF No. 92 because the testimony cited does not provide evidence of any general pattern or knowledge of Dey which was improper or related to pricing or reporting of AWP or WAC to the compendia. The testimony cited by Plaintiffs simply confirms that as part of its business, Dey was aware of state Medicaid reimbursement. However, Dey did not track how its products were being reimbursed by various state Medicaid agencies nor did it set prices based on such. (Reid Decl., Ex. 300, 5/15/08 Dey Dep. 185:7-186:1).

Dey incorporates its objections and responses set forth in response to US-SOF Nos. 89-91 as if fully set forth herein. Dey further disputes US-SOF No. 92 because it does not relate specifically to the drugs at issue and is immaterial to the issues before the Court.

93. In late 1993, Dey began to prepare for the launch of its cromolyn sodium inhalation solution product ("cromolyn"). Robert Mozak, Dey's Vice President of Sales and Marketing, prepared an October 15, 1993, memorandum to CFO Pamela Marrs and Charles Rice, who by then was President of Dey, in which Mozak set forth the pricing structure recommended for the upcoming launch. (Henderson Ex. 47.) The accompanying pricing description set forth in detail for Dey's cromolyn the AWP, the direct prices to different classes of trade, and the "spread to homecare pharmacists," which was $0.07 per vial. (*Id.*) The document also set forth similar information regarding the brand product with which Dey would compete, Intal (manufactured by Fisons), and showed that the "spread to homecare pharmacist" for Intal was $0.01. (*Id.*)

Dey's Response: Dey disputes US-SOF No. 93 because Exhibit 47 does not support the statements contained in US-SOF No. 93 and because it is immaterial to the issues before the Court.

As Plaintiffs admit in US-SOF No. 100, the hypothetical pricing scenarios set forth in Exhibit No. 47 never materialized. For example, the hypothetical pricing scenario set forth on page DL-TX-0091107 suggests an AWP of $44.40 for the 60-pack carton of cromolyn. However, the AWP that Dey provided when cromolyn was actually launched was $42.00 for the 60-pack. (6/26/09 Stiroh Decl., Figures A-K). Moreover, it is worth noting that the proposed pricing to retail pharmacies and wholesalers would yield virtually no spread under the hypothetical pricing scenario contained on page DL-TX-0091107.

Moreover, Plaintiffs incorrectly recite the numbers contained on page DL-TX-0091107 of Exhibit 47, and Dey therefore refers to the Exhibit itself as the best evidence of its content.

94. In December 1993, Robert Ellis, then a Dey marketing assistant, prepared detailed Marketing Plan for Cromolyn. (Henderson Ex. 48.) His marketing plan included an analysis of the profit that a homecare pharmacist would make from Medicare reimbursement. (Ex. 476.) It also included a section on pricing objectives that stated as one objective, "PROVIDE AN INCENTIVE TO RETAIL/CHAIN PROVIDERS TO PURCHASE DEY'S CROMOLYN BY INCREASING THE SPREAD ON MEDICARE/MEDICAID REIMBURSEMENTS." (*Id.*) The launch plan then set forth a pricing analysis similar to the one recommended in Mr. Mozak's October 15, 1993, memorandum. It recommended setting the AWP for the package of 60s (NDC 49502-0689-02) at $44.40, and the AWP for the package of 120s (NDC 49502-0689-12) at $82.80. (*Id.*)

Dey's Response: Dey disputes US-SOF No. 94. Dey also incorporates its response to US-SOF Nos. 82-84 as if fully set forth herein. Dey further states that when Dey launched cromolyn in May 1994, customers often refused to purchase the product because the spread was too low. A number of sales account call records reflect this. For example, on May 9, 1994, days after cromolyn was launched, a customer informed a Dey sales representative that the AWP for cromolyn was "way too low":

--STILL HAS PLENTY OF INTAL IN STOCK

-- SAID AWP IS "WAY TOO LOW" -> NO SPREAD AT ALL

(Reid Decl., Ex. 357).

On May 31, 1994, Dey sales representative Bill Hill visited Fred Payne, the Director of Pharmacy, and John Tasbenner, the Director of Respiratory Therapy at Grandview Hospital in Sewersville, Pennsylvania. According to Hill's call record recapping the visit, the Director of Respiratory "was thrilled w/ cromolyn packaging" and "will speak with Fred [the Director of Pharmacy] re: addition to formulary." (Reid Decl., Ex. 358). Fred, the Director of Pharmacy, however, "commented that Intal's spread was better than Dey's." (Reid Decl., Ex. 358; *see also* Reid Decl., Ex. 359 (May 24, 1994: "customers don't like low AWP on cromolyn"); Ex. 360 (June 1, 1994: "Carolyn and Louise were very receptive to cromolyn with the exception of product's spread); Ex. 361 (June 9, 1994: "concerned with lack of spread w/ cromolyn); Ex. 362 (June 10, 1994: "complained about lack of spread on cromolyn"); Ex. 363 (November 17, 1994: "had not stocked cromolyn because of poor spread")).

This remained an issue for approximately seven months until Dey lowered certain contract prices to customers to achieve pricing parity with the competition, not a spread advantage. Mr. Hill testified that Dey matched competitive prices for cromolyn sometime in the fall of November 1994 so that the features and benefits, instead of spread, would be determining factors when a customer decided to purchase Dey's cromolyn. As Mr. Hill testified:

> Q. And coming back to Exhibit 8 [*i.e.*,, Henderson Ex. 48] is it your recollection that when Dey's prices went down, the spread or profit as I think you referred to it, increased for purchasers of Dey's Cromolyn?
>
> A. I think it – to be clear, it put Dey at parity with the competition in the marketplace. There was not – Dey didn't go below competitive prices. They matched competitive prices in the market.

(Reid Decl., Ex. 364, Deposition of William Hill, dated 11/11/2008 ("Hill Dep."), at 156:11-20).

Mr. Hill also testified:

> Q. Was it your understanding then that a pricing objective of Dey was to provide incentive to retail and chain providers to use Dey's Cromolyn by increasing the spread on third-party payer reimbursements?

> A. Again, I don't think it was promoted to us as increase of spread. I think it was to provide a cost effective, safe, generic alternative that benefited the pharmacy and the patient.

(Reid Decl., Ex. 364, Hill Dep. 104:7-17).

Mr. Hill also testified that (referring to Henderson Ex. 48):

> Q. The fourth objective, which we discussed, did you also have as an objective in your sales calls to encourage the use of Dey's Cromolyn by pointing out the spread on third-party reimbursements?
>
> A. Again, I don't think that would be an accurate characterization. I think, again, we were selling a plastic vial product versus a brand product that was made in glass. So we had far different issues with mothers snapping open the top of a glass ampule and getting glass splinters in their fingers and having bloody fingers.
>
> So the packaging in Cromolyn was even a bigger sell than the price point, because at that point mothers didn't really care. They were just tired of getting bloody fingers from snapping the tops off of glass ampules.
>
> So again, that was probably a three or four prong strategy with the packaging, the right product at appropriate market pricing, and affording patient opportunity to save some money, too.

(Reid Decl., Ex. 364, Hill Dep. 128:16-129:17).

Mr. Hill testified that another factor that was attractive to providers was the lower cost of generics than brands:

> A. Another factor at this point in time, too, is an inventory holding cost for a customer. A customer would much rather have less capital tied up on a less expensive drug on a shelf as opposed to more money tied up in a more expensive brand product. That was a selling point in promoting generics over brands, so the working capital issue for a pharmacy.
>
> Q. Meaning because the generic was less expensive, you would have less money tied up with product on a shelf.
>
> A. That's correct.

(Reid Decl., Ex. 364, Hill Dep.131:1-12).

95. Mr. Ellis's recommended pricing for cromolyn was based on his understanding of the company's past experience with albuterol. (Henderson Ex. 40, at 29-31)

Dey's Response: Dey disputes US-SOF No. 95 because it mischaracterizes the testimony of Mr. Ellis and is immaterial to the issues before the Court. Dey also notes that while Mr. Ellis testified that his recommended pricing for cromolyn was based on his understanding of the company's past experience with albuterol, Mr. Ellis later testified that he was not following an established procedure and that he "really didn't have much idea what [he] was doing" when he recommended pricing for cromolyn:

> Q. And you say you followed your – your established procedure for – if I understood you correctly, when you were selecting your recommendations for AWP and for wholesale acquisition cost and for the other prices to classes of trade you followed an established procedure; is that right?
>
> A. No.
>
> Q. I'm sorry.
>
> A. There was no established procedure. I was basing my recommendation off what our historical pricing was relative to each other – relative to each class of trade. I was making an attempt. I really didn't have much idea what I was doing, but I was trying to be proactive in -- in guiding this process forward.

(Reid Decl., Ex. 330, Ellis Dep. 30:7-21).

96. Mr. Ellis also prepared an "Abridged Marketing Plan" for cromolyn sodium, dated January 1, 1994, which included as a pricing objective "PROVIDE AN INCENTIVE TO RETAIL/CHAIN PROVIDERS TO PURCHASE DEY'S CROMOLYN BY INCREASING THE SPREAD ON MEDICARE/MEDICAID REIMBURSEMENTS." (Henderson Ex. 49)

Dey's Response: Dey disputes US-SOF No. 96 because it is not supported by the document cited. Dey notes that Plaintiffs have provided an excerpt only of Exhibit 49, and there is no discussion of the launch AWP or WAC for cromolyn on the pages provided in Exhibit 49. As Mr. Hill testified, customers often refused to purchase Dey's cromolyn for several months after it was launched because the spread was too low. (*See* Dey's Response to US-SOF No. 94).

Dey also disputes US-SOF No. 96 because it is immaterial to the issues before the Court. Dey also incorporates its responses to US-SOF Nos. 92-93 and 81-82 as if fully set forth herein.

97. Charles Rice, Dey's President, would have been copied on the Abridged Marketing Plan. (Henderson Ex. 50, at 759.)

Dey's Response: Dey disputes US-SOF No. 97 as immaterial and irrelevant to the issues in this case. Dey further notes that the relevant testimony is set forth on page 758, not 759.

98. Mr. Rice testified as follows regarding the Abridged Marketing Plan:

> Q. And was the intent there to arrange a spread on medicare/medicaid reimbursement on Dey's generic cromolyn that was -- that was a greater spread than what the pharmacy would enjoy if they bought the brand?
>
> A. I believe that was probably what Mr. Ellis intended, yes.
>
> Q. And that was the intention of -- of Dey in terms of its pricing strategy whenever it launched a generic drug, correct?
>
> A. That's correct.
>
> Q. Build in a bigger spread than the pharmacist or provider could make if it -- than if -- than if it bought the brand drug?
>
> A. That's correct.

(*Id.*, at 759).

Dey's Response: Dey disputes US-SOF No. 98. Dey does not dispute that Mr. Rice provided the testimony set forth in US-SOF No. 98, but states that the excerpt of Mr. Rice's testimony is taken out of context and is therefore a mischaracterization. Dey also incorporates its responses to US-SOF Nos. 81-83 above which provides Mr. Rice's testimony on how Dey set price when launching a first-to-market generic such as cromolyn.

99. Dey launched the cromolyn product in April or May 1994. (Henderson Ex. 51; Dey-SOF ¶ 30.)

Dey's Response: Dey does not dispute the statements contained in US-SOF No. 99.

100. The AWPs that Dey subsequently reported for publication were slightly lower than the figures recommended in the Mozak memorandum and the Ellis launch plan

($42.00 and $84.00, respectively). (Henderson Ex. 51; Henderson Ex. 19, Summaries A7, A8.)

Dey's Response: Dey disputes US-SOF No. 100 because it is immaterial to the issues before the Court.

101. Dey collected information on the status of the coverage of cromolyn by each state's Medicaid program. (Henderson Ex. 52.)

Dey's Response: Dey disputes US-SOF No. 101 to the extent it suggests that Dey collected information about the reimbursement methodologies or reimbursement amounts that Medicaid provided for Dey's cromolyn in various states. Rather, Henderson Exhibit 52 is merely a memorandum, dated June 1, 1994, that states whether or not Dey's cromolyn is available to Medicaid patients in various states. (*See* Henderson Ex. 52).

102. In 1994, newly hired Dey sales representatives received training from Dey employee Debi Codute. (Henderson Ex. 15, at 143-144, 178-179; Henderson Ex. 53.)

Dey's Response: Dey disputes US-SOF No. 102 because it is not supported by the testimony that is cited. Mr. Hill testified that he personally received training from Ms. Codute, but did not testify that other Dey sales representatives received the same training. (Reid Decl., Ex. 364, Hill Dep. 143:16-144:4). Mr. Ricks-Bey's testimony is not credible for the reasons set forth in response to US-SOF No. 104 below. In any event, Mr. Ricks-Bey initially testified that he was not sure who trained him in 1994. (Reid Decl., Ex. 365, Deposition of Michael Ricks-Bey, dated 1/8/09 ("Ricks-Bey Dep."), at 41:1-16). Neither Mr. Hill's nor Mr. Ricks-Bey's testimony supports Plaintiffs' assertion that all newly hired sales representatives received training from Debi Codute.

103. When newly-hired sales representative William Hill received training from Debbie Codute in 1994, they covered how to educate pharmacists on the different reimbursements of Dey's product as compared to a competitor's product. The training included comparing the reimbursement on Dey's unit dose product as compared to a competitor's multidose product. That comparison was for the purpose of educating the pharmacist on the fact that the pharmacist could make more profit by

> selling Dey's unit dose product as compared to selling a competitor's multidose product. (Henderson Ex. 15, at 143-144, 178-179.)

Dey's Response: Dey disputes US-SOF No. 103 because it mischaracterizes the testimony cited and provides an incomplete description of the relevant testimony and is therefore misleading.

Mr. Hill worked at Dey as a low-level sales representative for a short period from April 1994 to August 1996. (Reid Decl., Ex. 364, Hill Dep. 287:18-20). During that time, Mr. Hill only called on Dey's local customers in Pennsylvania. (Reid Decl., Ex. 364, Hill Dep. 288:3-290:1). Mr. Hill did not call on national customers. (Reid Decl., Ex. 364, Hill Dep. 288:6-8). Mr. Hill worked in the pharmaceutical industry for approximately eight years before he started working at Dey in 1994. (Reid Decl., Ex. 364, Hill Dep. 297:8-10). Dey did not teach Mr. Hill about spread. (Reid Decl., Ex. 364, Hill Dep. 297:11-298:13). Mr. Hill was already informed about the concept of "spread" before he started working at Dey. (Reid Decl., Ex. 364, Hill Dep. 297:11-13). According to Mr. Hill, the "spread" was not something that Dey invented nor was it unique to Dey. (Reid Decl., Ex. 364, Hill Dep. 297:16-298:4).

Mr. Hill also testified that customers already had the information available and interest to determine what Dey's spread was versus a competitor and did not need to be educated about the topic. (Reid Decl., Ex. 364, Hill Dep. 299:7-304:10). As Mr. Hill testified:

> Q. So in any situation in which you may have discussed spread with a customer, you weren't telling the customer something that they didn't already know, correct?
>
> A. That's correct.
>
> Q. Or something that they didn't already have the ability to determine?
>
> A. That's correct.
>
> Q. Or something that they weren't already interested in?

A. Correct.

Q. Isn't it correct that in most of the conversations that you had with customers concerning the spread, it was the customer who initiated the topic?

A. I would agree.

(Reid Decl., Ex. 364, Hill Dep. 302:9-303:9). Mr. Tipton, a sales representative for Dey's national sales team, provided similar testimony. (Reid Decl., Ex. 345, 3/21/06 Tipton Dep. 265:3-268:7).

104. Former Dey sales representative Michael Ricks-Bey similarly received introductory training from Ms. Codute , as well as subsequent training, which included instruction on how much profit the pharmacist would make on Medicaid reimbursement (Henderson Ex. 53, at 54 :11- 55:4, 76:13 - 77:13)

Dey's Response: Dey disputes US-SOF No. 104. Dey incorporates its responses to US-SOF No. 102. Ricks-Bey has been shown to be a person who has a repeated and criminal propensity for untruthfulness and all of his testimony should be stricken for the reasons set forth hereafter.

Ricks-Bey was deposed pursuant to Magistrate Judge Bowler's order, dated December 18, 2008, at the Kit Carson Correctional Facility in Burlington, Colorado where he is currently serving a sentence of 20 years to life for felony sexual assault. (Reid Decl., Ex. 365, Ricks-Bey Dep. 18:2-10; Ex. 366). Ricks-Bey impersonated various professionals, including a chiropractor, a massage therapist, and a physician, in order to sexually assault women. (Reid Decl., Ex. 370; Ex. 367; Ex. 368; Ex. 369). Ricks-Bey used fraudulent credentials indicating he had a Ph.D in psychology, a masters degree in clinical psychology, and a certificate in massage therapy to deceive his victims. (Reid Decl., Ex. 370; Ex. 367; Ex. 368; Ex. 369). After he was released on bail, Ricks-Bey used a fake Denver vice office badge to obtain sexual favors through the threat of arrest. (Reid Decl., Ex. 370; Ex. 367; Ex. 368; Ex. 369). Ricks-Bey was arrested again in

April 2005 for crimes that included felony sexual assault, felony kidnapping, impersonating a peace officer, patronizing a child prostitute, and inducing child prostitution. (Reid Decl., Ex. 371; Ex. 372). After pleading guilty to felony sexual assault and other crimes, Ricks-Bey was sentenced to 20 years to life. (Reid Decl., Ex. 365, Ricks-Bey Dep. 18:2-5). At his sentencing hearing, Ricks-Bey sought probation so he could get out into society and work with children. (Reid Decl., Ex. 373).

Ricks-Bey was hired by Dey on March 1, 1994 and terminated on April 1, 1996. (Reid Decl., Ex. 365, Ricks-Bey Dep. 22:11-23:16). While at Dey, Ricks-Bey was employed as a district sales manager, which is the lowest possible sales position. (Reid Decl., Ex. 365, Ricks-Bey Dep. 223:2-8). Ricks-Bey admits that he had no authority to sign a contract on behalf of Dey or set sales strategy. (Reid Decl., Ex. 365, Ricks-Bey Dep. 33:21-34:16, 255:18-256:7). He had very little contact with the management of Dey. Indeed, he did not work at Dey's headquarters in Napa, California and only claims to have had two to three meetings with Dey's management at Dey's headquarters. (Reid Decl., Ex. 365, Ricks-Bey Dep. 26:8-27:22, 257:5-258:2). Rather he worked from his home in Aurora, Colorado and claims to have traveled to potential customers. (Reid Decl., Ex. 365, Ricks-Bey Dep. 26:8-27:22, 257:5-258:2). Ricks-Bey's territories were limited to Arizona, Colorado, New Mexico, and Utah. (Reid Decl., Ex. 365, Ricks-Bey Dep. 25:6-10). The United States concedes that it is not seeking any damages with respect to Arizona. (U.S. Consol. Mem. at p. 28, n.12).

During the deposition, Ricks-Bey repeatedly lied both about his time at Dey and why he was in prison. A pattern of lying and being out of touch with reality was evident throughout the deposition.

Ricks-Bey testified to a number of purported "facts" which are clearly contradicted by all of the evidence in the case. In particular, Ricks-Bey lied about his use of the document marked at his deposition as an exhibit and titled "Reimbursement Comparison Worksheet." When first asked about the "Reimbursement Comparison Worksheet," Ricks-Bey testified that he did not recall whether he used it on any sales calls. (Reid Decl., Ex. 365, Ricks-Bey Dep. 49:1-50:4.). Then Ricks-Bey flatly contradicted himself and claimed that he used the "Reimbursement Comparison Worksheet." (Reid Decl., Ex. 365, Ricks-Bey Dep. 85:14-86:17). When confronted with this inconsistency, Ricks-Bey denied his testimony from only a few hours earlier, which is clearly contradicted by the record. (Reid Decl., Ex. 365, Ricks-Bey Dep. 198:12-199:2).

Next, Ricks-Bey claimed that he used the "Reimbursement Comparison Worksheet" in 1994, which could not have been possible because it was not created until 1995. He testified that records of his calls to customers dated in 1994 referred to his use of the "Reimbursement Comparison Worksheet" with customers; he confirmed that he could not be mistaken. (Reid Decl., Ex. 365, Ricks-Bey Dep. 199:8-202:15). He further testified that Steve Robertson trained him to use the "Reimbursement Comparison Worksheet" when he began his employment in March or April of 1994. (Reid Decl., Ex. 365, Ricks-Bey Dep. 163:20-165:8, 166:11-18). The document itself, and the memorandum purportedly distributing it, are dated in March and April of 1995, and thus, Ricks-Bey could not have been telling the truth. (Reid Decl., Ex. 409; Ex. 410).

Ricks-Bey also claimed that he used the "Reimbursement Comparison Worksheet" for all of Dey's products. (Reid Decl., Ex. 365, Ricks-Bey Dep. 85:14-86:17). The only "Reimbursement Comparison Worksheet" that Dey created was for Dey's albuterol unit dose, so

Ricks-Bey's testimony that he used it for all of Dey's products cannot be true. (Reid Decl., Ex. 380, 3/1/06 Galles Dep. 417:2-19).

Ricks-Bey's inconsistent and false testimony was not limited to the "Reimbursement Comparison Worksheet." He testified that Dey was selling multi-dose albuterol in 1995, but this could not be true because Dey did not launch multi-dose albuterol until March 1996 (one month before Ricks-Bey was fired). (Reid Decl., Ex. 365, Ricks-Bey Dep. 69:9-70:18). He also testified that form 09-108-XX listed in Exhibit 13 refers to the AWP Price Listing Guide, p. 2 of Ex. 12, which compares AWPs of different companies; he confirmed that he was not mistaken. (Reid Decl., Ex. 365, Ricks-Bey Dep. 269:1-21). This is false. The form 09-108-XX refers to Average Wholesale Price Lists of Dey's drugs only, which do not include the AWPs of competitors. (*See, e.g.*, Reid Decl., Ex. 375; Ex. 376; Ex. 377; Ex. 378; Ex. 379).

Ricks-Bey also gave inconsistent testimony regarding the termination of his employment. First he testified that he was terminated because he did not "see eye to eye" with his boss' sales methods. (Reid Decl., Ex. 365, Ricks-Bey Dep. 160:20-161:14). Then, Ricks-Bey claimed that he filed a lawsuit against Dey after he was terminated based on discrimination. (Reid Decl., Ex. 365, Ricks-Bey Dep. 226:6-14).

Ricks-Bey's distorted sense of truth and reality was further exhibited by his testimony surrounding his current incarceration. Ricks-Bey disputed that he was an "inmate" in the prison, and instead, claimed he is a "detainee." (Reid Decl., Ex. 365, Ricks-Bey Dep. 17:17-19). Despite admitting he was serving a 20-year sentence at the beginning of the deposition, *see* Reid Decl., Ex. 365, Ricks-Bey Dep. 18:8-10, Ricks-Bey later denied he was serving any sentence, and instead, proclaimed he was being illegally detained and that the United States and Colorado do not have jurisdiction over him. (Reid Decl., Ex. 365, Ricks-Bey Dep. 182:1-4, 231:14-19).

Ricks-Bey believed he would be released by June 2009. (Reid Decl., Ex. 365, Ricks-Bey Dep. 231:20-232:5). Of course, Ricks-Bey is still in prison. (Reid Decl., Ex. 411). He based his claim that he is being illegally detained on his status as a member and Public Minister of the foreign nation, Washitaw Nation of Muurs, as supported by the 290 pages of documents that he created and brought with him to the deposition. (Reid Decl., Ex. 365, Ricks-Bey Dep. 17:7-10, 18:17-19:9, 175:8-177:3; Reid Decl., Ex. 374). Ricks-Bey further testified that he was born within the Washitaw Nation of Muurs, which is located in part of Virginia, and that the Washitaw Nation of Muurs existed before the United States. (Reid Decl., Ex. 365, Ricks-Bey Dep. 191:12-192:6). Ricks-Bey claims he has dual citizenship with this "tribe" and the United States. (Reid Decl., Ex. 365, Ricks-Bey Dep. 179:3-11).

Ricks-Bey also claimed he was an "expert" and requested the contact information of the DOJ attorney present at the deposition so that he could request payment for his testimony. (Reid Decl., Ex. 365, Ricks-Bey Dep. 192:10-193:7, 194:16-195:21, 234:6-13). He claimed that the documents establishing himself as a member of the purported foreign nation, Washitaw Nation of Muurs, supports his claim that he is an expert. (Reid Decl., Ex. 365, Ricks-Bey Dep. 194:16-195:21).

In granting the Government's motion to take the deposition of Ricks-Bey, Magistrate Judge Bowler forewarned the Government: "I think you'll have credibility issues with this witness." (Reid Decl., Ex. 408, at 128:3-5). Ricks-Bey's inability to testify truthfully and consistently during the deposition proved Magistrate Judge Bowler correct.

105. In January 1994 Dey held a National Sales Meeting in Napa, California. Substantially all of the Dey sales force attended. (Henderson Ex. 54, at 95-97 & Depo. Ex. 778; Henderson Ex. 1, at 134-135.) At the 1994 convention, Dey sales manager Ross Uhl gave a presentation called "Working a Homecare Pharmacy." (Henderson Ex. 54, at Dep. Ex. 778); (Henderson Exhibit 55.)

Dey's Response: Dey disputes US-SOF No. 105. Dey does not dispute that it held a national sales meeting in Napa, California in January 1994. Dey disputes that "[s]ubstantially all of the Dey sales force attended" because the testimony cited by Plaintiffs does not support this statement.

Dey does not dispute that Mr. Uhl made a presentation at the meeting. However, Mr. Uhl testified that he believed he provided the presentation as part of a breakout meeting in which the meeting attendees were broken out into small groups, possibly on a rotation basis. (Reid Decl., Ex. 326, Uhl Dep. 93:13-25).

Mr. Uhl testified that the purpose of the presentation he gave at the national sales meeting in 1994 was to explain why a homecare pharmacy was interested in taking on Medicare patients. (Reid Decl., Ex. 326, Uhl Dep. 104:3-15). When asked if the purpose of the presentation was to provide instruction on selling points to use with customers, Mr. Uhl disagreed:

> Q. Are these selling points that you're educating your national sales staff to use when marketing their products to homecare pharmacies?
>
> A. No. This was just an attempt on my part to help them try to understand what's in it for the homecare pharmacy and why are they interested at all in taking on a Medicare patient. I don't recall at any time that this was to be used outside of this meeting to discuss reimbursement. Because as I mentioned before, that's really not our area where we're trying to sell against competition or put product in the pharmacy. But this was an explanation to try to explain to them how a pharmacy and a DME dealer both profited and worked by purchasing either our product or a competitor's or compounding it and then getting a reimbursement from either a Medicaid or Medicare provider.

(Reid Decl., Ex. 326, Uhl Dep. 103:25-104:15).

There is nothing inappropriate about a pharmaceutical company being aware of third party reimbursement for its products. As Ms. Burnham Selenati testified, knowledge of Medicaid reimbursement was "essential" to running the business:

> Q. And as a logical matter, you would expect that a pharmaceutical company couldn't really run its business without being aware of how Medicaid reimbursed on some basis, right?
>
> A. No. It was something that was essential to running your business.

(Reid Decl., Ex. 325, 5/5/05 Burnham Selenati Dep. 321:8-13).

106. Items that Dey personnel wished to place on the agenda for a National Sales Meeting had to be reviewed and approved by management before they could be placed on the agenda. (Henderson Ex. 54, at 96:16-20; Henderson Ex. 56, at 91-92.)

Dey's Response: Dey disputes US-SOF No. 106 because it is irrelevant and immaterial to the issues before the Court. Dey also disputes US-SOF No. 106 because it is not supported by the testimony to which it cites and because it raises an issue of fact as to who in management reviewed and approved items before they were placed on an agenda for a national sales meeting. Mr. Uhl agreed that he would have sent a draft of his presentation for the 1994 national sales meeting through his "chain of command for review and approval" but he does not identify who those individuals were. (Reid Decl., Ex. 326, Uhl Dep. 93:16-20). Ms. Collie testified that the individuals involved in the review process depended on the period of time. (Reid Decl., Ex. 329, Collie Dep. 92:4-10).

107. In his presentation at the 1994 National Sales Meeting, Mr. Uhl sought to explain how a pharmacy and a durable medical equipment (DME) dealer both profited and worked by purchasing either Dey's product or a competitor's or compounding it and then getting a reimbursement from either a Medicaid or a Medicare provider. (Henderson Ex. 54, at 95-97, 106-108.) The presentation handout stated that Medicare and Medicaid reimbursed based on AWP. (Henderson Ex. 54, at Dep. Ex. 778.) Mr. Uhl understood that providers were motivated in part by reimbursement. (Henderson Ex. 54, at 108.)

Dey's Response: Dey disputes US-SOF No. 107 because it mischaracterizes the testimony of Mr. Uhl and the document it cites. Dey incorporates its response to US-SOF No. 105 as if fully set forth herein.

108. In January 1995, Dey held another National Sales Meeting in Scottdale, Arizona. (Henderson Ex. 57, at Dep. Ex. 9.) A large number of sales representatives from all over the country attended.

Dey's Response: Dey does not dispute that it held a national sales meeting in Scottsdale, Arizona in January 1995. Dey disputes that "a large number of sales representatives from all over the country attended" because Plaintiffs cite no evidence to support this statement. According to page DL-TX-0096743 of Exhibit 57, approximately fifty individuals attended the meeting, and those fifty included not only sales representatives, but employees from Dey's marketing, finance, and distribution departments as well. (Henderson Ex. 57 at DL-TX-0096743).

109. The 1995 National Sales meeting included three workshops, each of which was mandatory. (Henderson Ex. 15, at 157-159.) One of the workshops taught strategies for converting customers from using the albuterol sulfate multi-dose product sold by Dey's competitors (Schering and Warrick) to using Dey's Albuterol Sulfate Unit Dose product. (Henderson Ex. 15, at 170; Henderson Ex. 57 (Hill Dep. Ex. 9 at p. DEY-058-0204.)

Dey's Response: Dey disputes US-SOF No. 109. Dey does not dispute that the 1995 national sales meeting included three workshops and that a topic of one of the workshops involved converting multi dose albuterol customers to unit dose albuterol.

Dey also notes that another workshop held on the same day focused on a hospital study that showed the benefits to the patient of using unit dose albuterol instead of multi dose albuterol. (*See* Henderson Ex. 57). Several Dey employees testified that an important selling tool in converting customers from multi dose albuterol to unit dose albuterol was to discuss the benefits to the patient as set forth in the hospital study. (Reid Decl., Ex. 364, Hill Dep. 162:1-17; Ex. 336, 2/6/03 Galles Dep. 51:1-9).

110. Dey employees Ross Uhl and Debi Codute presented information and a handout at this workshop. (Henderson Ex. 15, at 170; Ex. 57 at DEY-058-0204.)

Dey's Response: Dey disputes US-SOF No. 110 because it is immaterial to the issues before the Court and is not supported by the cited testimony and document.

111. According to testimony of William Hill, the handout for this workshop, (Henderson Ex. 58) was made available to all the sales representatives who attended the workshop. (Henderson Ex. 15, at 157-159.)

Dey's Response: Dey disputes US-SOF No. 111 because it is immaterial to the issues before the Court and because it is not supported by the testimony to which it cites. Specifically, there is no mention on pages 157-159 about who Henderson Exhibit 58 was made available to. On pages 163:19-164:4, Mr. Hill testified that:

> Q. Do you have an understanding as to whether or not these materials were made available to all of the sales reps who attended that workshop?
>
> A. All I can speak is what I saw in my group, is that everybody would have received the materials.

(Reid Decl., Ex. 364, Hill Dep. 163:19-164:4).

When asked if other groups would have received the materials, Mr. Hill indicated that he had no personal knowledge of that occurring and was guessing at the answer:

> Q. So if they follow the same approach for the other groups, they would have received these materials as well?
>
> A. I guess you could assume that, yes.

(Reid Decl., Ex. 364, Hill Dep. 164:6-11).

112. The handout states,

- AWP Reimbursement: Why it's important, how it's calculated and what it means in terms of reimbursement from the third-party payers to the managed care organizations.
- Why "Multi-dose to Unit dose" Albuterol Conversion makes good business sense for the Customer Base.
- The dramatic effect the conversion has in real dollars yielding significant gain to the bottom line profit of the targeted accounts.

(Henderson Ex. 58 (underscore in original)).

Dey's Response: Dey disputes US-SOF No. 112. Dey incorporates its response to US-SOF Nos. 109 and 111 as if fully set forth herein. Dey refers to the entirety of Henderson Exhibit No. 58 as the best evidence of its content.

113. There was discussion at the workshop about each of these topics. (Henderson Ex. 58, at 164-167.)

Dey's Response: Dey disputes US-SOF No. 113 because it is immaterial to the issues before the Court. Dey incorporates its response to US-SOF Nos. 114-115 and 117 as if fully set forth herein.

114. Former Dey sales representative William Hill testified:

> Q. And what do you recall about why converting from multidose to unit dose Albuterol would make good business sense for the customer?
> A. Well, based on some assumptions that were gathered in the field in a couple different markets -- specifically I guess that Debi Codute had done the majority of their research in this area with unit test and multidose. It was her conclusion that there would be opportunity both for a profit alternative for a pharmacy and then also the other things we talked about earlier with product safety and lack of infection risk.

(Henderson Ex. 15, at 164-165.)

Dey's Response: Dey disputes US-SOF No. 114 because it provides an incomplete, and therefore, misleading excerpt of Mr. Hill's testimony. Mr. Hill also testified that the assumption that a pharmacist would make more profit dispensing unit dose albuterol instead of multi dose albuterol turned out to be incorrect in many instances because the assumption failed to take into account the reimbursement a pharmacist would receive for saline when dispensing a multi dose product, thus yielding no reimbursement benefits for unit dose in many instances. As Mr. Hill testified regarding this flaw in the worksheet (referring to page DEY-057-0031 of Henderson Exhibit 58):

> A. Actually I could point out to you on page one where there is a flaw that we found out after the fact with the assumptions on the multidose. If you look on line three that it says zero for reimbursement for saline?

Q. Yes.

A. Actually, and you will probably see, I know they are not in the call reports, but for patients to use this, it was a multidose concentrate where you needed to add saline to it.

So, in fact, a lot of the plans did cover a disproportionately high amount, they did pay for saline.

So the flaw is when we run out and use this in the field and showed this to pharmacies, and they said, okay, yeah, they understood the concept here, and then they would put in their own numbers, actually some disproportionately high reimbursements were being paid for water, saline.

So the impact of – in a lot of cases I agree with you, that the Dey product was still more profitable, but the fact that there was a zero in here – in the sales meeting there always was a zero. Nobody knew that any third parties would pay for more, but it stands to reason to appropriately dose a product, you needed, number one, to add the saline to dilute it to the right concentration, and number two, you need to use a saline to rinse it out because you didn't want the infection in your – risk in your nebulizer.

Q. So you later learned that for multidosed products that at least some third-party payers did reimburse for saline?

A. Right.

Q. Is it fair to say that whoever authored this didn't realize that?

A. I think they may have missed that detail, yes.

Q. And you would agree that even with the correcting for that error, the profit per patient per year for the Dey albuterol product was greater than for the multidose competitive product?

A. Actually, believe it or not, there were cases in Philadelphia where we ran the model that plans paid so much for the saline, that actually a multidose was more profitable than the unit dose.

It completely shot holes – in certain cases – now there are certain cases it's not a one size fits all. There were certain cases where Dey was more profitable to unit dose, but there were other cases to use a multidose plus a saline was a more profitable option for a retail pharmacist.

(Reid Decl., Ex. 364, Hill Dep. 173:2-175:15).

115. The handout at the 1995 National Sales Meeting also included two worksheets. One was entitled "Albuterol Unit Dose Worksheet," which referred to Dey's Albuterol

Sulfate Unit Dose product, and which was a vehicle by which sales representatives could calculate the profit that a pharmacist would potentially realize by dispensing the Dey unit dose product. The other was entitled "Albuterol Multidose Worksheet," which was for the multi-dose product sold by Dey's competitor, Schering or Warrick, and was intended to illustrate the potential profit realized by dispensing the competitor's product. The last line, with the words "Gain in Profit," was designed to quantify the higher profit realized from selling Dey's unit dose as compared to the profit realized from selling the competitor's multidose product. (Henderson Ex. 15, at 167-169; Ex. 58.)

Dey's Response: Dey disputes US-SOF No. 115. Mr. Hill testified that the reimbursement worksheet actually did not actually demonstrate that a pharmacist could usually make more profit selling unit dose albuterol than multi dose albuterol because the worksheet failed to take into account the reimbursement a pharmacist would receive for saline when dispensing a multi dose product, thus yielding no reimbursement benefits for unit dose in many instances. (*See* Dey's response to US-SOF No. 114 above).

116. Former Dey sales representative William Hill recalled that the scenarios in these worksheets were presented at the workshop. (Henderson Ex. 15, at 179.)

Dey's Response: Dey disputes US-SOF No. 116 because it is not supported by the cited testimony.

117. It was a marketing objective of Dey to convert potential customers from purchasing a competitor's multi-dose albuterol to purchasing Dey's unit dose albuterol.

Dey's Response: Dey disputes US-SOF No. 117 as immaterial to the issues before the Court. Dey does not dispute that it was a marketing objective of Dey to convert potential customers from purchasing a competitor's multi-dose albuterol to purchasing Dey's unit dose albuterol. Dey disputes, however, that there is anything wrong or unethical about doing so. Dey also notes that it had a variety of ways of promoting the use of unit dose albuterol over multi dose albuterol and that the reimbursement worksheet referred to in US-SOF No. 114 played an insignificant role in Dey's efforts to convert customers from multi dose albuterol to unit dose albuterol.

Ms. Marrs, Dey's corporate designee, testified that the conversion of multi dose albuterol to unit dose albuterol was driven by a variety of safety issues:

> What I know about the worksheet is that it was – the whole conversion of multidose to unit dose was driven by a variety of safety issues.
>
> Multidose to unit dose there were advantages from a sterility standpoint, from a dosing standpoint.
>
> As part of a way to get the customers to convert to the unit dose one of the Sales Reps – or I don't know – maybe there were more than one – had this thought that the spread sheet would be created, and it was actually put together by Todd Galles after Steve Robertson and/or others, I don't know if there were others involved – thought that this would be a good tool.
>
> It was one of many tools that the Sales Reps used for a limited period of time.
>
> I have seen testimony that suggests that it was helpful to the Reps, and I've seen testimony that suggests it was – I think the term was, you know, it died a quick death because it was not useful to the Reps.
>
> But it was – it was not the focus of the attempt to – or it's my understanding it was not the focus of the attempt to convert business from multidose to unit dose. It was one of the many facets of the – of the campaign to make that conversion.
>
> And, actually, multidose today rarely exists. There have been – there were huge sterility problems, and most people stopped using multidose for that very reason.

(Reid Decl., Ex. 300, 5/15/08 Dey Dep. 232:21-234:9).

When asked if unit dose albuterol cost more to third-party payors than multi dose albuterol, Mr. Galles testified:

> The patient is getting a lot more benefit from a unit-dose than from a multi-dose, and so I don't think you can take that out of context. A unit-dose product offers a sterile product with Benzalkonium Chloride. I mean, there's all kinds of benefits that a patient is getting as a better product. So it's not pure price, it's price and feature benefit to a patient, and, you know, that's a decision that people have to make – all along.

(Reid Decl., Ex. 336, 2/6/03 Galles Dep. 51:1-11).

Mr. Tipton testified the product features of albuterol unit dose that were attractive to customers:

> A. Well, they would be ease of – ease of delivery of the product, wastage, how effective the product was, were there – are there preservatives that are included in the drug that would interact with the patient's ability to – to metabolize the drug and how it was packaged and on and on an on.

(Reid Decl., Ex. 345, 3/21/06 Tipton Dep. 280:4-9).

When Mr. Tipton was asked about the use of the reimbursement worksheet to convert customers from multi dose albuterol to unit dose albuterol, Mr. Tipton testified that he believed the worksheet was "short-lived and I – I would say less than two years" and "died a death on its own":

> I think this was short-lived, using – using this document, as I remember, and, you know, I wouldn't necessarily place any more emphasis on this than – in terms of our overall selling strategy than the fact that our preservative – our product was preservative free, had a better package, we had a better reputation, et cetera.

(Reid Decl., Ex. 333, 2/13/03 Tipton Dep. 86:11-17; 267:16-24).

118. Dey personnel created a "Reimbursement Comparison Worksheet. Dey manager Todd Galles and Dey employee Steve Robertson were involved in its creation. (Henderson Ex. 59, at 346, 350, and Dep. Ex. 37.) Mr. Galles was assigned to work with Mr. Robertson to come up with a workable format and create a tool for the sales force to use. (Henderson Ex. 59, at 347348.)

Dey's Response: Dey disputes US-SOF No. 118 because it does not refer specifically to the drugs at issue and therefore mischaracterizes the testimony of Mr. Galles. Dey does not dispute that Mr. Galles testified that he created a reimbursement comparison worksheet that compared multi dose albuterol to unit dose albuterol and that Mr. Robertson helped him to do so. (Reid Decl., Ex. 380, Deposition of Todd Galles, dated 3/1/06 ("3/1/06 Galles Dep."), at 347:19-348:3; 417:2-418:3). Mr. Galles also testified that the only reimbursement worksheet he created compared multi dose albuterol to unit dose albuterol. (Reid Decl., Ex. 380, 3/1/06 Galles Dep.

417:2-418:3). Mr. Galles testified that he did not create worksheets for any other generic drug. (Reid Decl., Ex. 380, 3/1/06 Galles Dep. 417:2-418:3).

119. On April 5, 1995, Todd Galles sent a memo to Dey's sales force, the subject of which was "Marketing Update - AWP Pricing and Profit Gain Worksheet." In the memorandum he stated:

> At the national sales meeting our Managed Care Group presented the reimbursement advantages of our unit-dose packaging over multidose products. Several requests were made for additional information so we thought a memo in order.
>
> Attached for your review and use are an AWP price listing guide and a Profit Gain Worksheet for use on your retail calls. The AWP price listing is company confidential and intended only for your reference and not to be left behind with any customers. The worksheet is more impactful when you work through it with a customer, but it can be left. [Thanks to Steve Robertson for the format.]
>
> If you have any questions about the material be sure to discuss it with your manger. It can be a very compelling story when presented properly.
>
> Continued good selling!

(Henderson Ex. 60 (brackets in original).)

Dey's Response: Dey disputes US-SOF No. 119 because it is immaterial to the issues before the Court. Dey incorporates its responses to US-SOF Nos. 114-115 and 117-118 as if fully set forth herein.

120. The Reimbursement Comparison Worksheet was officially approved by Helen Burnham, Robert Mozak, and Charles Rice in April 1995. (Henderson Ex. 61, at 700-703 and Dep. Ex. 44 and 45.)

Dey's Response: Dey disputes US-SOF No. 120 because it is immaterial to the issues before the Court. Dey further states that at the time the reimbursement worksheet was approved, the Government had not yet indicated that it might have issues with discussing the spread with customers. In any event, there is no evidence that the reimbursement worksheet was used outside of 1995 and 1996 or outside the limited context of comparing Dey's unit dose albuterol with multi dose albuterol. (*See* Dey's responses to US-SOF Nos. 119, 121, 152).

Dey further states that Mr. Mozak officially disapproved the use of the reimbursement worksheet in 1999. (Reid Decl., Ex. 380, 3/1/06 Galles Dep. 369:14-370:21). At this point, Dey had received the first subpoena from OIG, which was the first time the Government had indicated that it might have issues with using the spread as a marketing tool, and as soon as Dey became aware of the government's feelings on this point, it stopped its marketing efforts. (Reid Decl., Ex. 380, 3/1/06 Galles Dep. 370:10-3-21).

121. New editions of the Reimbursement Comparison Worksheet were approved and copyrighted in 1996 and 1999, as indicated in the footers in the new editions. (Henderson Ex. 62.)

Dey's Response: Dey disputes US-SOF No. 121. Plaintiff's assertion that a new edition of the reimbursement comparison worksheet was approved and copyrighted in 1999 is contradicted by Pages DL-TX-0170971 and DL-TX-0170972 of Henderson Exhibit 61. Page DL-TX-01710971 is a copy approval sheet for a 1999 version of the reimbursement comparison worksheet that Mr. Galles submitted to Mr. Mozak. It contains Mr. Mozak's handwritten direction that the version proposed in 1999 of the worksheet "cannot be used per RFM 3/29/99." (*See* Henderson Ex. 61). Mr. Galles confirmed that Mr. Mozak told him that Dey would not use the worksheet Mr. Galles proposed in 1999:

> Q. Now let's go back to the Exhibit 37 [referring to Henderson Exh. 61] that we were talking about before the break. And specifically that page DL-TX – you may already be there, Mr. Galles. The one with your handwriting on it across the – running diagonally. Are you?
>
> A. 971?
>
> Q. Yes. Page DL –
>
> A. Yes.
>
> Q. – TX-0170971. Now, you do remember that Mr. Mozak told you to no longer use this reimbursement comparison worksheet, right?
>
> A. Well, this – seeing this refreshed my memory, yes.

> Q. And he wasn't just directing that you personally, but he was saying, look, Dey Labs will no longer be using the reimbursement comparison worksheet, correct?
>
> A. I would interpret it that way.

(Reid Decl., Ex. 380, 3/1/06 Galles Dep. 369:14-370:9).

Mr. Mozak testified that Dey stopped using the worksheet in mid-1996. (Reid Decl., Ex. 344, 3/13/03 Mozak Dep. 801:1-13). Dey's corporate representative, Pam Marrs, testified that the reimbursement worksheet was not used for a long period of time in the mid-1990s. (Reid Decl., Ex. 346, 10/2/08 Dey Dep. 790:15-791:9). Mr. Tipton, head of Dey's national sales force in the mid-late 1990s, testified that the worksheet was "short lived…less than two years" and "died a death on its own." (Reid Decl., Ex. 333, 2/13/03 Tipton Dep. 86:11-17, 267:16-18, 29:6-12).

Mr. Galles testified that he did not believe he was doing anything wrong when he created the worksheet in 1995. (Reid Decl., Ex. 380, 3/1/06 Galles Dep. 418:4-9). Mr. Galles also testified that when he met with attorneys from the Texas Attorney General's office, the attorneys did not tell him that he did anything wrong when he created the worksheet. (Reid Decl., Ex. 380, 3/1/06 Galles Dep. 418:10-21).

122. In mid-1995 Dey Marketing Manager Helen Burnham learned from Ross Uhl, a Dey sales representative who at the time sold Dey drugs in Florida, that Dey had lost a customer's business because the spread on the albuterol product of a competitor, Warrick, was greater than the spread on Dey's product. (Henderson Ex. 1, at 109-110, 192.)

Dey's Response: Dey disputes US-SOF No. 122. Dey incorporates its responses to US-SOF Nos. 67-71. Dey does not dispute that Ms. Burnham Selenati testified that she learned in mid-1995 from Ross Uhl that Dey had lost a customer's business because the spread on Warrick's albuterol product was greater than the spread on the Dey product, but disputes the accuracy of Ms. Burnham Selenati's testimony to the extent it conflicts with Mr. Uhl's testimony

on the subject. (Reid Decl., Ex. 326, Uhl Dep. 61:2-63:19). Dey also disputes Ms. Burnham Selenati's testimony because it constitutes inadmissible hearsay.

Mr. Uhl testified that Jeff Hunt, the pharmacy manager of Pharmacy Factors, informed Uhl sometime prior to August 1994 that Pharmacy Factors was going to switch some of its patients to Warrick's albuterol product because of the favorable reimbursement rate on the Warrick product. (Reid Decl., Ex. 326, Uhl Dep. 58:1-22; 61:2-62:12).

123. Florida's Medicaid program at the time reimbursed for drugs based in part on WAC, and Florida used the FDB Blue Book. (Henderson Ex. 42, at p. DL0050034 DL0050035; Henderson Common Ex. 24.)

Dey's Response: Dey disputes US-SOF No. 123. Dey states that during the relevant time period in the mid-1990s, Florida reimbursed for prescription drugs at the lowest of (i) the usual and customary price charged to the general public, (ii) the EAC plus the applicable dispensing fee, which was WAC + 7% in most cases, (iii) federal upper limit ("FUL") plus the applicable dispensing fee, or (iv) state maximum allowable cost ("MAC") plus the applicable dispensing fee (from July 1, 1994). (Reid Decl., Ex. 381; Ex. 382, Deposition of Jerry Wells, dated 5/25/05, ("5/25/05 Wells Dep."), at 604:11-21).

124. Helen Burnham wrote a memorandum dated May 30, 1995, to Dey's sales force that stated:

> Re: Albuterol WAC Pricing
>
> Attached is a copy of a fax sent to all database managers to update their records with out wholesale acquisition cost (WAC) for albuterol.
>
> As you know, the following states are now using WAC instead of AWP to calculate Medicaid reimbursement:
>
> Alabama
> Colorado
> Florida
> Maryland
> Massachusetts

> WAC is not representative of our published wholesale list prices, but like AWP, is used for calculation of reimbursement. Our updated WAC values are in line with the Warrick WAC values provided by First Data Bank and should level the playing field for Medicaid reimbursement.
>
> Please give me a call if you have any questions.

(Henderson Ex. 64.)

Dey's Response: Dey disputes US-SOF No. 124. Dey incorporates its responses to US-SOF Nos. 67-71 as if fully set forth herein. In addition, Dey does not dispute that Ms. Burnham Selenati wrote this memorandum, but disputes that the content of the memorandum is accurate. Specifically, Ms. Burnham Selenati states in the memorandum that "WAC is not representative of our published wholesale list prices, but like AWP, is used for calculation of reimbursement." No Dey witnesses that were shown this sentence agreed that this description of WAC was correct. Indeed, all the Dey witnesses that provided testimony on this issue testified that WAC was, in fact, representative of Dey's wholesale list prices. (Reid Decl., Ex. 335, Bronstein Dep. 209:10-21; Ex. 329, Collie Dep. 173:19-174:25, 177:16-23; Ex. 330, Ellis Dep. 215:24-216:10; Ex. 336, 2/6/2003 Galles Dep. 262:11-22, 305:4-14; Ex. 337, 11/1/2001 Mozak Dep. 187:19-188:10; Ex. 332, 10/30/2001 Rice Dep. 176:14-177:2; Ex. 333, 2/13/2003 Tipton Dep. 219:21-220:7, 221:1-10; Ex. 326, Uhl Dep. 220:10-17; Ex. 334, Upp Dep., at 144:9-145:24, 197:19-198:2).

125. Attached to the May 30, 1995, Burnham memorandum was a fax from Dey to FDB notifying FDB that, "For your records, we are updating our prices as follows:

NDC NUMBER	PRODUCT DESCRIPTION	SIZE	UNITS PER CARTON	AWP	WAC
49502-697-03	Albuterol Sulfate Inhalation Solution 0 .083%	3 mL	25	$30.25	$24.75
49502-697-33	Albuterol Sulfate Inhalation Solution 0 .083%	3 mL	30	$36.60	$29.70
49502-697-60	Albuterol Sulfate Inhalation Solution 0 .083%	3 mL	60	$72.60	$59.40

(Henderson Ex. 64.)

Dey's Response: Dey disputes US-SOF No. 125. Dey does not dispute that this fax was sent to First DataBank on or about May 30, 1995. However, the circumstances surrounding the delivery of the fax raise an issue of material fact. Dey incorporates its responses to US-SOF Nos. 67-71 as if fully set forth herein.

126. The May 30, 1995, Memorandum was distributed to Dey's Sales and Marketing personnel. (Henderson Ex. 37, at 229-30.)

Dey's Response: Dey disputes US-SOF No. 126 because it is contrary to the testimony of numerous other witnesses and thus raises an issue of fact. Dey does not dispute that Ms. Burnham Selenati testified that she believed that the May 30, 1995 memorandum was distributed to Dey's sales and marketing personnel. However, none of the sales and marketing personnel that were shown a copy of the memorandum during deposition recalled ever receiving the document in 1995. Specifically, seven Dey employees testified that they never saw the May 30, 1995 Memorandum and were unaware that Dey's WAC was ever changed in 1995. (Reid Decl., Ex. 329, Collie Dep. 171:2-10; Ex. 330, Ellis Dep. 216:11-17; Ex. 331, Gmeiner Dep. 183:21-184:6, 232:7-17; Ex. 332, 10/30/2001 Rice Dep. 124:21-125:1; Ex. 333, 2/13/2003 Tipton Dep. 220:8-14; Ex. 326, Uhl Dep. 54:11-25; Upp Dep. 129:17-130:1). Three Dey employees testified that they saw the memo for the first time in 1997 while searching for documents responsive to a subpoena. (Reid Decl., Ex. 335, Bronstein Dep. 70:9-13, 288:14-289:4; Ex. 336, 2/6/2003 Galles Dep. 24:3-24, 164:7-11; Ex. 337, 11/1/2001 Mozak Dep. 187:19-23; Ex. 338, 11/6/2002 Mozak Dep. 561:17-562:1, 575:2-15).

127. The Hearst Corporation, the owner of FDB, has produced from FDB files a substantially identical copy of the May 30, 1995, fax attached to Helen Burnham's memorandum. (Henderson Ex. 32.)

Dey's Response: Dey does not dispute the statements contained in US-SOF No. 127.

128. Effective June 1, 1995, FDB published the WAC prices as shown above. (Henderson Ex. 19.) The FDB prices remained in effect until January 1, 1998. (*Id.*)

Dey's Response: Dey disputes US-SOF No. 128 and incorporates its responses to US-SOF Nos. 67-71 as if fully set forth herein. As set forth in response to US-SOF Nos. 67-71, Dey does not dispute that First DataBank published the WAC prices contained in Exhibit 19 on or about June 1, 1995. Dey disputes that it is responsible for those prices remaining in effect until January 1, 1998. Dey corrected the WAC prices on December 4, 1995 and thus is not responsible for First DataBank's failure to correct the prices until January 1, 1998.

129. In November 1995, Dey prepared to launch its Albuterol Sulfate Metered Dose Inhaler ("MDI"), 17g, NDC 49502-0303-17. Todd Galles prepared a Launch Plan, dated November 1995. (Henderson Ex. 65.)

Dey's Response: Dey does not dispute the statements contained in US-SOF No. 129.

130. The launch plan set forth sales and marketing objectives. It stated as "Assumptions" that "There will be generic competition within 3 months after launch," and "Average selling price can be maintained at $12/unit in first 12 months." (*Id.*)

Dey's Response: Dey does not dispute that Exhibit 65 provides a hypothetical "Assumption" that "There will be generic competition within 3 months after launch," and "Average selling price can be maintained at $12/unit in first 12 months," but disputes that these assumptions ever materialized. Indeed, Plaintiffs cite no evidence to demonstrate otherwise.

131. The launch plan included a table entitled, "MDI Pricing" that compared proposed pricing for Dey's new MDI product and the brand products, which were Ventolin and Proventil. The launch plan stated that the AWP for the Dey product would be "$21.70 (Proventil AWP10%)," which was approximately ten percent below the AWP of the Proventil product. (*Id.*)

Dey's Response: Dey does not dispute the statements contained in US-SOF No. 131.

132. The "MDI Pricing" table also set forth "Direct Pricing" to various classes of customers, including Wholesaler, Generic Distributor, Mail Order, and Homecare Pharmacy, with recommended prices ranging from a high of $17.06 to a low of $13.70. (*Id.*)

Dey's Response: Dey does not dispute that Exhibit 65 provides recommended prices to various classes of customers, but disputes that these recommended prices were actually implemented. Indeed, Plaintiffs cite no evidence to demonstrate otherwise.

133. Dey launched the drug in January 1996. (Henderson Ex. 66.) Dey set the AWP at $21.70 and notified Publishers accordingly. (Henderson Ex. 67.)

Dey's Response: Dey does not dispute that it launched its albuterol MDI product in January 1996, but disputes the remainder of the statements contained in US-SOF No. 133. Exhibit 67 indicates only that Dey provided an AWP of $21.70 to RedBook, but no other price reporting services. Moreover, what happened to any prices that Dey provided to pricing compendia was in the control of the compendia, and not Dey. A review of the prices published by the various compendia show that the prices were updated at various times, and not all of the compendia list the same price at the same time. (Reid Decl., Ex. 322, at 2; Ex. 300, 5/15/08 Dey Dep. 135:1-136:10).

134. First DataBank published an AWP for this drug of $21.70. (Henderson Ex. 19, Summary A1.)

Dey's Response: Dey does not dispute US-SOF No. 134 except to state that Dey also provided a WAC at the same time it provided AWP. (6/26/09 Stiroh Decl., Figures A-K). Dey reported reductions to the WAC on a regular basis. (6/26/09 Stiroh Decl., Figures A-K; Dey responses to US-SOF Nos. 67-71). The WAC, and all reductions to WAC, was as available to state and federal governments as was the AWP through First DataBank and other price reporting services. (6/26/09 Stiroh Decl., Figures A-K).

135. By fax memorandum dated January 9, 1996, Dey's CEO reported to Dey's parent company that "The albuterol MDI launch has thus far exceeded our expectations, over $1 million in sales after five days on the market! And many of the wholesaler orders are yet to be processed." (Henderson Ex. 68.)

Dey's Response: Dey disputes US-SOF to the extent it tries to paint an inaccurate portrayal of Dey's sales of albuterol MDI. Dey does not dispute that Plaintiffs have correctly, but selectively, quoted from a fax memorandum dated January 9, 1996, authored by Charles Rice. Dey notes that while Mr. Rice may have stated that MDI had sales of $1 million in the first week it was on the market, total net sales for albuterol MDI in 1996, the year the product was launched, were $14,756,223. (*See, e.g.*, Reid Decl., Ex. 383; Ex. 384; Ex. 385; Ex. 386; Ex. 387; Ex. 388; Ex. 389; Ex. 390; Ex. 391; Ex. 392; Ex. 393; Ex. 394).

136. In mid-1996, Dey prepared to launch Ipratropium Bromide Inhalation Solution 0.02%. A Marketing Plan was prepared by Todd Galles, Eve Gmeiner, and Debra Bronstein. (Henderson Ex. 69.)

Dey's Response: Dey disputes US-SOF No. 136. Dey does not dispute that it prepared to launch ipratropium in mid-1996, but disputes that Exhibit 69 is the actual marketing plan that was used for the product. Handwritten notations throughout the document indicate that Exhibit 69 is a draft.

137. The Marketing Plan observed that there were two competitors who distributed ipratropium bromide solution: Boehringer Ingelheim ("BI"), which distributed the branded product Atrovent, and Roxane Laboratories, a subsidiary of Boehringer, who distributed the generic equivalent. (*Id.*, at DL-TX-0092993.) The Marketing Plan devoted four pages to discussion of these two competitors. (*Id.*, at DL-TX-0092993 - 0092996.)

Dey's Response: Dey disputes US-SOF No. 137 because it is irrelevant and immaterial to the issues before the Court. Dey also disputes US-SOF No. 137 because it attempts to mischaracterize the contents of Exhibit 69. Exhibit 69 is a 41-page draft marketing plan that contains eight different topics. The fact that the draft contains four pages of discussion about Dey's anticipated competitors is insignificant and immaterial. The draft also contains four pages concerning the disease that is treated with ipratropium, two pages of information about the way the drug itself works, and four pages of information about the patient population for ipratropium.

(*See* Henderson Ex. 69). Moreover, in the four pages of the draft that discuss the expected competitors for ipratropium, there is no discussion of the competitors' AWPs or spreads. (*See* Henderson Ex. 69, at 13-16). Moreover, the term "spread" appears nowhere in the draft. (*See* Henderson Ex. 69).

138. The Marketing Plan included a "Product Comparison Chart" that compared the features of the Dey ipratropium bromide product and the Roxane and BI products. (*Id.*, at DL-TX-00930004 [sic].)

Dey's Response: Dey disputes US-SOF No. 138 because it is irrelevant and immaterial to the issues before the Court. Dey does not dispute that page DL-TX-0093004 of Exhibit 69 contains a "Product Comparison Chart" that compares the features of Dey's ipratropium product to the Roxane and BI products. Dey further notes that the "Product Comparison Chart" contained on page DL-TX-0093004 contains no references to pricing. Dey incorporates its responses to US-SOF Nos. 136-37 as if fully set forth herein.

139. The Dey Marketing Plan for ipratropium bromide also included the following:

> **VII. MARKETING STRATEGIES AND TACTICS**
>
> STRATEGY
>
> **6. Set price and AWP to enhance sales while maximizing customer loyalty.**
>
> TACTICS
>
> 1. Develop price matrix comparing competitive listed prices.
> 2. Notify pricing databases and verify information is loaded into their systems.
> 3. Establish pricing guidelines for customer classes based upon volume and ability to move market share.
> 4. Prepare reimbursement worksheets.

(Id., at p. DL-TX-0093016.)

Dey's Response: Dey disputes US-SOF No. 139. Dey does not dispute that Plaintiffs have correctly, but selectively, quoted a passage from a 41-page draft marketing plan for ipratropium. Dey disputes that the proposed or hypothetical events stated in this passage ever

occurred. Indeed, Plaintiffs cite no evidence demonstrating that the hypothetical events did occur. In fact, Exhibit 70, which is the final ipratropium launch plan does not contain this passage.

Specifically, Plaintiffs have provided no evidence that reimbursement worksheets were ever prepared for Dey's ipratropium products. Moreover, Todd Galles, the product manager for ipratropium, testified that reimbursement worksheets were never prepared or used with Dey's ipratropium products. (Reid Decl., Ex. 380, 3/1/06 Galles Dep. 417:14-16, 452:24-453:9).

Moreover, Plaintiffs fail to explain what it means to "[s]et price and AWP to enhance sales while maximizing customer loyalty." Plaintiffs have not cited any testimony to explain what is meant by this passage. Moreover, Todd Galles, the marketing product manager who drafted the ipratropium marketing plan and had overall responsibility for the ipratropium launch, testified that Dey priced ipratropium, not to "enhance sales while maximizing customer loyalty," but to match Roxane's pricing: "We would price – in the case of, say, ipratropium we priced at Roxane pricing and it wasn't – if you came in and undercut them you just start a pricing spiral which wouldn't make sense for anybody so you came in and you priced basically at the same level." (Reid Decl., Ex. 336, 2/6/03 Galles Dep. 185:6-11; Ex. 380, 3/1/06 Galles Dep. 452:24-453:9).

Dey also disputes SOF No. 139 as immaterial to the issues before the Court.

140. The Dey Marketing Plan also included the following table:

Ipratropium Pricing Guidelines:								
	DEY LABORATORIES				**ROXANE**		**BOEHRINGER**	
Customer Type:	25's	25's Per vial	60's	60's Per vial	25's	25's Per vial	25's	25's Per vial
AWP (% off brand)	44.10 -10%	1.76	105.60	1.76	44.06 -10.1%	1.76	49.00	1.96
WAC	25.50 -48%	1.02 -48%	60.90 -48.2%	1.015 -48.2%	26.44* -46%	1.06 - 46%	40.80	1.63

(% off *Atrovent* AWP)								
Independent Retail Hospital List (% above WAC)	27.29 +7%	1.09 +7%	65.10 +7%	1.085 +7%	27.83	1.11		

(*Id.*, at p. DL-TX-0093021.)

Dey's Response: Dey disputes US-SOF No. 140. Dey does not dispute that Plaintiffs have correctly, but selectively, quoted a passage from a 41-page draft marketing plan for ipratropium.

This passage supports Mr. Galles' testimony that Dey priced ipratropium to match Roxane's pricing. Todd Galles testified that Dey priced ipratropium to match Roxane's pricing: "We would price – in the case of, say, ipratropium we priced at Roxane pricing and it wasn't – if you came in and undercut them you just start a pricing spiral which wouldn't make sense for anybody so you came in and you priced basically at the same level." (Reid Decl., Ex. 336, 2/6/03 Galles Dep. 185:6-11).

141. A Fall 1996 Launch Manual, distributed to Dey Sales and Marketing personnel, included lengthy discussion of anticipated competition with Boehringer Ingelheim and Roxane. (Henderson Ex. 70.)

Dey's Response: Dey disputes US-SOF No. 141 because it mischaracterizes the contents of Exhibit 70. Dey refers to the entirety of Exhibit 70 as the best evidence of its content.

142. In early January 1997, Dey launched the Ipratropium Bromide products, 49502685-03 (carton of 25), 49502-685-60 (carton of 60). (Henderson Ex. 71 (mis-dated January 1996); Henderson Ex. 72.) Dey reported, and FDB and Red Book published, an AWP for the package of 25s that was $44.10, the same as the AWP stated in the Ipratropium Pricing Guidelines in the Marketing Plan. (*Id.*)

Dey's Response: Dey disputes US-SOF No. 142 because it is not supported by the cited documents. Dey does not dispute that it launched ipratropium in January 1997 and that it provided an AWP of $44.10 to First DataBank and Redbook which was published by those

databases. Dey further states that it also provided a WAC of $25.50 to First DataBank at the same time it provided the AWP. (6/26/09 Stiroh Decl., Figures A-K). Dey reported reductions to the WAC on a regular basis. (6/26/09 Stiroh Decl., Figures A-K; Dey's responses to US-SOF Nos. 67-71). The WAC, and all reductions to WAC, was as available to state and federal governments as was the AWP through First DataBank and other price reporting services. (6/26/09 Stiroh Decl., Figures A-K).

143. In the second quarter of 1997, the average price to the retail pharmacy class of trade for Dey's Ipratropium package of 25s was $19.21, and the spread was 129%. By the second half of 2003, prices had dropped to the point where the spread was 710%. (Henderson Ex. 19, at Summary A9.)

Dey's Response: Dey disputes US-SOF No. 143 as unsupported by the evidence cited and incorporates its response to US-SOF No. 72 as if fully set forth herein. As set forth more fully in response to US-SOF No. 72, Dey does not dispute that Mr. Platt's calculations are mathematical calculations of what Mr. Platt purports to be average selling prices for various Dey drugs. However, Dey does dispute that Mr. Platt's calculations are probative evidence that the average prices as calculated by Mr. Platt should have been reported by Dey in the pricing compendia. Dey further states that dollar margins and spreads on generic prescriptions are exaggerated and misleading when presented in percentage terms, and in the case of Dey, are the result of generic price competition. (*See* Dey-SOF No. 62; 6/26/09 Bradford Decl. ¶ 13).

144. In August 1997, Dey introduced ipratropium bromide in a carton of 30, NDC #49502-0685-33, partly in response to Roxane's launch of a 30s pack. Dey notified the pricing Publishers of its AWP and WAC. (Henderson Ex. 73.)

Dey's Response: Dey does not dispute US-SOF No. 144.

145. Documents produced by Dey indicate aggressive price competition between Dey and Roxane. (Henderson Ex. 74.)

Dey's Response: Dey disputes US-SOF No. 145 because it is vague and because the documents cited are insufficient to support Plaintiffs' assertion. Dey never raised its AWP to

compete with Roxane. (*See* Dey-SOF No. 70; 6/26/09 Stiroh Decl., Figures A-C). Dey lowered its contract prices over time on ipratropium and this was reflected in Dey's published, declining WAC prices for ipratropium. (6/26/09 Stiroh Decl., Figures A-K). Dey's lower contract prices were also reflected in the quarterly AMPs that Dey reported to CMS. (*See* Dey-SOF Nos. 90, 104-105).

146. In early 1996 or before, Dey decided to compete directly in the albuterol multi-dose market. In March 1996, Dey launched Albuterol Sulfate Multidose Solution, .5%, 20ml, NDC 49502-0196-20. (Henderson Ex. 75.) In 1999 the product package was changed and sold under the NDC #49502-0205-01.

Dey's Response: Dey does not generally dispute US-SOF No. 146, but notes that in 1999, the NDC for Dey's multi dose albuterol product changed to NDC 49502-010501.

147. This product was a concentrated form of albuterol sulfate that required, in the normal course of usage, measuring the appropriate amount of the drug and storing the bottle for reuse. (Henderson Ex. 76.) The Dey product was manufactured by Glaxo Wellcome, the manufacturer of the brand version, Ventolin. (*Id.*) At the time of the launch, several other companies competed in this generic market. (*Id.*, at DL-TX-0076236.)

Dey's Response: Dey does not dispute US-SOF No. 147.

148. A Launch Manual, dated March 1996, was prepared by Dey product manager Todd Galles. (Henderson Ex. 76; Henderson Ex. 77 at 95; Henderson Ex. 78 at 476.)

Dey's Response: Dey does not dispute US-SOF No. 148.

149. The Launch Manual included a version of the Reimbursement Comparison Worksheet substantially similar to the one circulated to Dey's sales staff with Mr. Galles's April 5, 1995, memorandum (see paragraph 119 above).

Dey's Response: Dey does not dispute US-SOF No. 149. Dey incorporates its response to US-SOF No. 119 as if fully set forth herein.

150. The Launch Manual contained an "ALBUTEROL MULTI-DOSE PRICING" table showing an AWP of $14.90 for the Dey product and prices to different classes of customer, including "wholesaler," "homecare pharmacy," and "Retain/Hospital/MedSurg List Price," with the prices for these classes of customer shown as $7.90, $6.90, and $8.70, respectively.

(Henderson Ex. 76, at DL-TX-0076256.)

Dey's Response: Dey disputes US-SOF No. 150 in part. The AWP for the Dey product is listed as $14.99, not $14.90.

151. On or about March 4, 1996, Dey sent the Launch Manual to its sales force with a cover memorandum by Mr. Galles dated March 4, 1996. The memorandum stated:

> We are very pleased to announce the addition of another Glaxo Wellcome product to our comprehensive line albuterol products. The addition of this product now moves us into the prestigious position of having the most extensive respiratory product line of any generic manufacturer. The multidose niche of the respiratory market has not directly been accessible to us in the past. However, now you can target accounts that you were not able to convert, and accounts that you know have a sizable multidose business. Try to leverage this business to gain even more Unit-dose business.
>
> In this launch manual you will find a copy of the presentation you saw recently at your sales meeting, including the launch plan, market overview, sales direction, our pricing matrix terms, literature, a training module and copies of all announcement mailings. In addition, we included the "Multidose to Unit-dose Conversion" reprint and worksheet, and the "Retail Profit Gain" worksheet. You used both successfully last year. Re-familiarize yourselves with these two pieces so they can work to your advantage again. These pieces should reinforce the importance of our Unit-dose business and also help you strategize where to pick up multidose business. Let us not forget that Unit-dose should remain our top priority.

(Henderson Ex. 76.)

Dey's Response: Dey disputes US-SOF No. 151. Dey incorporates its responses to US-SOF Nos. 117 and 152 as if fully set forth herein. Dey does not dispute that Plaintiffs have accurately cited to Mr. Galles' March 4, 1996 cover memorandum, but disputes that the content of Mr. Galles' memorandum is correct. Dey disputes that Mr. Galles' statement that "You used both [worksheets] successfully last year" is correct as it conflicts with the testimony of other Dey sales representatives who stated that the worksheet "died a fast death," was based on inaccurate assumptions, and was not widely used. (*See* Dey's responses to US-SOF Nos. 117 and 152).

152. According to Mr. Galles, the Reimbursement Comparison Worksheet was "one of the tools that was provided for sales reps to use accordingly with their account." (Henderson Ex. 78, at 354.)

Dey's Response: Dey disputes US-SOF No. 152 because it takes Mr. Galles' testimony out of context and therefore mischaracterizes it. Mr. Galles testified that, in 1995, he created a reimbursement comparison worksheet that could be used in the limited situation of trying to convert a customer from multi-dose albuterol to unit-dose albuterol. (Reid Decl., Ex. 380, 3/1/06 Galles Dep. 417:2-418:3). Sales representatives were required to request copies of the worksheet before they would be provided them. (*See* Henderson Ex. 15 at Dep. Ex. 16).

Mr. Galles, who was Dey's generic product manager from 1994-2001 and was responsible for the launches of albuterol multidose, albuterol MDI, and ipratropium, testified that he did not create reimbursement comparison worksheets for any other drugs. (Reid Decl., Ex. 380, 3/1/06 Galles Dep. 10:7-17; 12:3-22, 417:2-418:3).

Mr. Galles also testified that he went on sales visits to customers and never used a reimbursement comparison worksheet with a customer. Nor did Mr. Galles ever see a Dey sales representative use a reimbursement comparison worksheet with a customer. (Reid Decl., Ex. 380, 3/1/06 Galles Dep. 419:8-420:3).

Todd Galles testified that:

> Q. Did you ever go on sales visits to customers with Dey sales representatives?
>
> A. Yes.
>
> Q. Did you ever use Exhibit 461 [Henderson Exh. 62] with a customer?
>
> A. No.
>
> MR. ANDERSON: Objection, form.
>
> Q. Did you ever see a Dey salesperson use Exhibit 461 with a customer?

MR. ANDERSON: Objection, form.

A. No.

Q. Did you ever use a reimbursement comparison worksheet with a customer?

A. No.

Q. Did you ever see a Dey salesperson use a reimbursement comparison worksheet with a customer?

A. No.

Q. On any of the customer visits that you went on with Dey sales representatives did you ever see a reimbursement comparison worksheet presented to a customer?

A. No.

(Reid Decl., Ex. 380, 3/1/06 Galles Dep. 419:8-420:3).

Jim Gist, a long-time Dey sales representative covering certain territories in Texas from 1980 until at least 2002, testified that he did not use the reimbursement comparison worksheet. (Reid Decl., Ex. 395, Deposition of James Gist, dated 11/5/2002 ("Gist Dep."), at 21:6-22:21, 181:12-184:20, 204:13-18). Mr. Gist also testified that he chose not to use the worksheet because it would have required too much effort to use it with a customer, not because he thought there was anything wrong with using it. (Reid Decl., Ex. 395, Gist Dep. 181:12-185:2).

Helen Burnham Selenati testified that she occasionally went on sales calls with Ross Uhl, Debi Codute, and Jim Gist. (Reid Decl., Ex. 325, 5/5/05 Burnham Selenati Dep. 375:6-376:13). Ms. Burnham Selenati also testified that she never saw anyone at Dey use a reimbursement worksheet in front of a customer. (Reid Decl., Ex. 325, 5/5/05 Burnham Selenati Dep. 375:25-376:4, 373:15-22). Mr. Tipton testified that while the worksheet may have been used, it "was short-lived" or "died a death on its own." (Reid Decl., Ex. 333, 2/13/03 Tipton Dep. 86:11-17,

267:16-18). Moreover, Plaintiffs have presented no evidence showing that any sales resulted from the use of the worksheets.

Chris Gurchiek, a Dey sales representative and regional manager from April 1996 to 2002, testified that AWP had never been a factor in selling Dey's product for him or anyone that worked for him. (Reid Decl., Ex. 396, Deposition of Chris Gurchiek, dated 5/3/02 ("Gurchiek Dep."), at 10:12-11:3, 93:2-94:8). Mr. Gurchiek also testified that he did not have much understanding of how Medicaid and Medicare reimbursed for Dey's products. (Reid Decl., Ex. 396, Gurchiek Dep. 109:7-110:10). Mr. Gurchiek also testified that he was not aware of conversations at Dey in which AWP was compared to cost. (Reid Decl., Ex. 396, Gurchiek Dep. 253:10-18).

Willia Tate, Dey's sales director from September 1997 to 2002, testified that she never witnessed any occasion where Medicaid reimbursement was used within Dey as a sales or marketing tool. (Reid Decl., Ex. 397, Deposition of Willia Tate, dated 2/7/03 ("Tate Dep."), at 16:15-17, 19:1-6, 32:11-16, 219:11-220:5).

153. Mr. Galles testified that he "got feedback that reps liked it, that regional managers liked it." (*Id.*, at 353-354.)

Dey's Response: Dey disputes US-SOF No. 153 because it is immaterial to the issues before the Court and because it mischaracterizes the testimony of Mr. Galles. Mr. Galles also testified that he never actually saw a salesperson use a reimbursement worksheet with a customer during any of the sales calls that he attended. (Reid Decl., Ex. 380, 3/1/06 Galles Dep. 419:8-420:3). Mr. Galles also testified that he himself never used the reimbursement worksheet with a customer. (Reid Decl., Ex. 380, 3/1/06 Galles Dep. 419:8-20).

Dey also disputes US-SOF No. 153 because it ignores the testimony of other Dey witnesses who testified that the worksheet was not well-received by the sales force. For

example, Jim Gist, a long-time Dey sales representative covering certain territories in Texas from 1980 until at least 2002, testified that he did not use the reimbursement comparison worksheet. (Reid Decl., Ex. 395, Gist Dep. 21:6-22:21, 181:12-184:20, 204:13-18). Mr. Gist also testified that he chose not to use the worksheet because it would have required too much effort to use it with a customer, not because he thought there was anything wrong with using it. (Reid Decl., Ex. 395, Gist Dep. 181:12-185:2). Mr. Tipton testified that the worksheet "was short-lived" and used "less than two years" and "died a death on its own." (Reid Decl., Ex. 333, 2/13/03 Tipton Dep. 86:11-17, 267:16-24). Mr. Hill testified that the assumption that a pharmacist would make more profit dispensing unit dose albuterol instead of multi dose albuterol turned out to be incorrect in many instances because the assumption failed to take into account the reimbursement a pharmacist would receive for saline when dispensing a multi dose product, thus yielding no reimbursement benefits for unit dose in many instances. (Reid Decl., Ex. 364, Hill Dep. 173:2-175:15).

154. Former Dey sales representative William Hill testified:

> Q. Coming back to Exhibit No. 12, did you use this worksheet or a worksheet like this when you made sales calls for Dey?
> MS. GIULIANA: Objection to the form.
> THE WITNESS: Occasionally I would, sometimes in a formal sense. I don't recall using this one specifically, but I would be more of a legal pad and sort of model things out rather than assuming that's what a customer's business model might be, something I had prepared, conceptually talk about how this would fit in their business model and then take a legal pad and sort of have them work through and plug and play with their own numbers.
> BY MR. HENDERSON:
> Q. And did you use this in connection with the Dey unit dose Albuterol product?
> A. Yes.

(Henderson Ex. 15 at 181:21-182:16).

Dey's Response: Dey disputes US-SOF No. 154 because it is incomplete and therefore mischaracterizes Mr. Hill's testimony on this topic. Mr. Hill also testified:

> Q. Earlier today Mr. Henderson showed you a document called a reimbursement comparison worksheet, correct?
>
> A. Yes.
>
> Q. Now, is there anything that would go into any of the blanks in that worksheet that a customer didn't already know?
>
> MS. HANSCOM: Objection, form.
>
> A. No.
>
> Q. So the customer already had the information available to fill in any of the blanks in that worksheet?
>
> MS. HANSCOM: Objection, form.
>
> A. Yes, they would.
>
> Q. So in any situation where you sat down with a customer and reviewed that document with a customer, you are not telling the customer anything he didn't already know?
>
> MS. HANSCOM: Objection, form.
>
> A. No.
>
> Q. And did you ever use the reimbursement comparison worksheet with respect to Dey's Ipratropium product?
>
> MS. HANSCOM: Objection, form.
>
> A. No, I did not.
>
> Q. Did you ever use the reimbursement worksheet with respect to Dey's Cromolyn product?
>
> MS. HANSCOM: Objection, form.
>
> A. Not that I recall.
>
> Q. Did you ever use reimbursement comparison worksheet or the concept set forth in that worksheet to try to convert a customer from a competitor's unit dose Albuterol product to Dey's unit dose Albuterol product?

MS. HANSCOM: Objection, form.

A. Not on a unit dose to unit dose scenario, no.

(Reid. Decl., Ex. 364, Hill Dep. 303:11-305:8).

155. The Reimbursement Comparison Worksheet was on a "Literature Request Form" that was used by Dey sales representatives to request Dey promotional materials. (Henderson Ex. 15, at 203-205, and Depo. Ex. 16.)

Dey's Response: Dey disputes US-SOF No. 155 because it mischaracterizes the testimony of Mr. Hill and the document that it cites and because it is not limited to a specific time period. Dey also disputes US-SOF No. 155 because it is immaterial to the issues before the Court.

Dey does not dispute that Mr. Hill testified that he used a "literature request form" to request promotional materials. However, Mr. Hill was only employed at Dey from April 1994 to August 1996 and thus cannot provide admissible testimony as to Dey's practices outside of this time period. (Reid Decl., Ex. 364, Hill Dep. 287:18-20).

Moreover, Depo. Ex. 16 is dated "Revised -- 5/7/95" and there is no evidence that the document, as revised, was in effect during any other time period at Dey. Plaintiffs have cited no testimony or similar documents that suggest that Depo. Ex. 16 was in effect during any other period. Dey also notes that the literature request form includes approximately 70 other pieces of literature that a sales representative could have requested on or about May 7, 1995. Moreover, the literature request form marked as Depo. Ex. 16 indicates that 50 copies of the UCSF hospital study appear to have been requested while only 5 copies of the reimbursement comparison worksheet were requested.

156. Michael Ricks-Bey, who was a Dey sales representative from 1994 to 1996, used the reimbursement comparison worksheet on his account calls. (Henderson Ex. 53, at 85-86.)

Dey's Response: Dey disputes US-SOF No. 156. Dey incorporates its responses to US-SOF Nos. 102 and 104. As set forth more fully in response to SOF No. 104, Rick-Bey's testimony regarding the "Reimbursement Comparison Worksheet," is not credible. (*See* Dey's response to SOF No. 104.)

Dey further states that Ricks-Bey's territory was limited to Arizona, Colorado, New Mexico, and Utah for only the period of March 1, 1994 to April 1, 1996, and he did not make any sales calls on any customers outside of his territory. (Reid Decl., Ex. 365, Ricks-Bey Dep. 258:22-260:15, 261:21-262:1). The Government concedes that it is not seeking any damages with respect to Arizona. (U.S. Consol. Mem. at p. 28, n.12.)

157. When Dey launched its albuterol sulfate multi-dose product, Dey sales representative understood that the sales of Dey's unit dose product was still a top priority. (Henderson Ex. 15, at 237.) Hill understood that it was "Dey's policy that sales reps continue to use the reimbursement comparison worksheet in order to convert customers from using a multidose competitor product to Dey's unit dose product at least where it seemed appropriate in the circumstances." (*Id.*, at 237-238.)

Dey's Response: Dey disputes US-SOF No. 157 and incorporates its responses to US-SOF Nos. 151-156.

158. By the mid-1990s, major wholesalers were providing their pharmacy customers with computer software that allowed the customer to compute spreads and compare spreads among related drug products. (Henderson Ex. 79, at 183:7-185:11.)

Dey's Response: Dey disputes US-SOF No. 158 because it is immaterial to issues before the Court and because it provides an incomplete and therefore inaccurate description of the relevant facts. First, Mr. Johnston, Dey's contract manager and long-term Dey employee, testified that he was unaware that pharmacies had software available to them to help them calculate the spread. (Reid Decl., Ex. 306, 12/10/08 Johnston Dep. 211:6-212:21, 11:20-12:1, 10:15-17). Moreover, Plaintiffs provide no evidence that anyone at Dey was aware of these

computer programs. Nor have Plaintiffs cited any Dey document in which this software is referenced.

Dey disputes US-SOF No. 158 to the extent it attempts to characterize pharmacies and other providers as uninformed and unsophisticated entities that had no idea what the spread was or how it affected them until it was force-fed to them by representatives of manufacturers or wholesalers. Rather, customers typically were sophisticated, informed, and knew exactly what the spread was. (Reid Decl., Ex. 335, Bronstein Dep. 254:24-255:5; Ex. 364, Hill Dep. 301:9-303:9; Ex. 326, Uhl Dep. 231:25-232:22; Ex. 333, 2/13/03 Tipton Dep. 36:9-22, 93:6-14, 255:2-16; Ex. 305, 7/10/08 Dey Dep. 347:9-20, 349:15-350:4). Debra Bronstein, Dey's marketing director during the mid-late 1990, testified:

> Q. Did you feel that – that Dey educated these customers in the importance of reimbursements – reimbursement as a source of profit to them or did you feel that they understood this?
>
> A. They educated Dey, not the other way around. They educated us, the management, they educated the reps, they educated us about reimbursement.

(Reid Decl., Ex. 335, Bronstein Dep. 254:24-255:5, 28:22-23, 31:12-14).

Ross Uhl testified that GeriMed and MHA were two of his customers and they clearly had an understanding of the reimbursement process. Uhl did not have to teach them about the subject of spread. (Reid Decl., Ex. 326, Uhl Dep. 231:25-232:22).

Mr. Hill testified that most discussions about spread were initiated by customers. (Reid Decl., Ex. 364, Hill Dep. 303:4-9). The situation in 1995 with Warrick's WAC for albuterol was brought to Dey's attention by a Dey customer in Florida. (Reid Decl., Ex. 326, Uhl Dep. 61:2-63:12). Moreover, in April 2003, it was Dey's customers that informed Dey that First DataBank had reduced Dey's AWPs for the subject drugs and demanded that corrective action be taken. (*See* Dey's response to US-SOF No. 82).

159. On or about October 31, 1997, Dey received the first federal subpoena from the HHS OIG seeking documents concerning Dey's pricing practices. (Henderson Ex. 80.)

Dey's Response: Dey does not dispute that the OIG issued a first subpoena to Dey on or about October 31, 1997 (the "1997 OIG subpoena"), but disputes Plaintiffs' characterization of the contents of the 1997 OIG subpoena and the documents sought by it. Dey refers to the 1997 OIG subpoena as the best evidence of its contents. (*See* Henderson Ex. 80).

160. In April 2000, Dey received a Civil Investigative Demand from the State of Texas Office of Attorney General requesting documents concerning Dey's pricing practices. (Henderson Ex. 81.)

Dey's Response: Dey disputes US-SOF No. 160 because it is irrelevant and immaterial to the issues before the Court. Dey does not dispute that it received a Civil Investigative Demand from the State of Texas Office of Attorney General (the "Texas CID") in or about April 2000, but disputes Plaintiffs' characterization of the contents of the Texas CID and the documents sought by it. Dey refers to the Texas CID as the best evidence of its contents. (*See* Henderson Ex. 81).

161. In late July or early August 2000, Dey received a second federal subpoena from the HHS OIG seeking documents concerning Dey's pricing practices. (Henderson Ex. 82.)

Dey's Response: Dey does not dispute that it received a second federal subpoena from the HHS OIG in or about late July or early August 2000 (the "2000 OIG subpoena"), but disputes Plaintiffs' characterization of the contents of the 2000 OIG subpoena and the documents sought by it. Dey refers to the 2000 OIG subpoena as the best evidence of its content. (*See* Henderson Ex. 82).

162. On October 30, 2001, Dey's President Charles Rice testified on October 30, 2001, as follows:

> Q. Did Dey Laboratories ever, or Dey, Inc., ever market the spread between reimbursement amounts and the actual cost for Dey

> products in an effort to get customers to purchase Dey Laboratories' Albuterol?
> MR. HUDSPETH: Objection to form.
> A. I'm sorry. Could you repeat the question?
> MR.BREEN: Would you please read the question back.
> (Requested portion was read.)
> THE WITNESS: To my knowledge, we did not. There have been occasions where customers has - have asked us to identify "the spread." but an active marketing promotion which was solely based on "the spread," no. Nor would we condone that.

(Henderson Ex. 83, at 161:25 - 162:14.)

Dey's Response: Dey does not dispute that Mr. Rice gave this testimony, but disputes the implication Plaintiffs draw from the same. The parties hotly contest what "marketing the spread" means. Dey's senior management did not condone manipulating AWP to increase the spread in order to market it. (*See* Dey's response to US-SOF No. 81). This does not mean that sales representatives were not prepared to address spread issues as required by customers.

163. Mr. Rice testified further:

> Q. That was my question. Is it wrong to promote Dey's product over Warrick's product based upon a bigger spread? That's my question.
> MR. HUDSPETH: Objection to form.
> THE WITNESS: In -- in my view?
> Q. (By Mr. Breen) Yes.
> A. Yes.
> Q. Why?
> A. Because it's against what Dey Laboratories represents.
> Q. And what does Dey Laboratories represent that makes that wrong?
> A. We treat our customers fairly. We treat our products fairly. We sell our products on the merits of the product -- the clinical, the safety, and the product presentation itself. We do not sell on the spread, period.

(*Id.*, at 164:10-165:24.)

Dey's Response: Dey does not dispute that Mr. Rice gave this testimony, but disputes the implication Plaintiffs draw from the same. The parties hotly contest what "marketing the

spread" means. Dey's senior management did not condone manipulating AWP to increase the spread in order to market it. (*See* Dey's response to US-SOF No. 81). This does not mean that sales representatives were not prepared to address spread issues as required by customers.

164. Mr. Rice on October 30, 2001, also testified that "Marketing the spread is actually going out and promoting this to customers without customers requesting it. We do not create promotional materials. This is not on Dey letterhead. I don't know if this ever went to the customer and I have said - again, I'll repeat: I would not condone it and I do not believe Bob Mozak would condone it." (*Id.*. at 168:21 - 169:2.)

Dey's Response: Dey does not dispute that Mr. Rice gave this testimony, but disputes the implication Plaintiffs draw from the same. The parties hotly contest what "marketing the spread" means. Dey's senior management did not condone manipulating AWP to increase the spread in order to market it. (*See* Dey's response to US-SOF No. 81). This does not mean that sales representatives were not prepared to address spread issues as required by customers.

165. On November 1, 2001, Robert Mozak testified to his understanding of what the term "spread" meant, and to his understanding of whether or not Dey had ever engaged in the practice of marketing this spread to its customers.

Dey's Response: Dey disputes US-SOF No. 165 because it is unsupported by any evidence.

166. He testified:

> Q. So, is spread the difference between what is reimbursed to those vendors and the amount that they actually paid to acquire the product?
> A. Yes.
> Q. Is it Dey's policy to market the spread in its interaction with its customers?
> A. No, it is not.
> Q. Has Dey ever engaged in the practice of marketing the spread?
> A. Not to my knowledge.
> Q. If it came to your attention that your employees were engaged in the practice of marketing the spread, would you condone that practice?
> A. No, I would not.

> Q. I'll represent to you that Mr. Rice was, shall we say adamant that he did not condone the practice of marketing the spread. Do you share that feeling?
> A. Yes, I do.
> Q. Can you tell us why?
> A. Well, I just -- I don't think it's -- it's - it's proper. We have never -- that has never been the policy of the company to market on that basis. We market on the basis of the product attributes.

(Henderson Ex. 84, at 85:19 - 86:24.)

Dey's Response: Dey does not dispute that Mr. Mozak gave this testimony, but disputes the implication Plaintiffs draw from the same. The parties hotly contest what "marketing the spread" means. Dey's senior management did not condone manipulating AWP to increase the spread in order to market it. (*See* Dey's response to US-SOF No. 81). This does not mean that sales representatives were not prepared to address spread issues as required by customers.

167. In response to the HHS OIG subpoenas served to Dey in 1997 and 2000, as well as subpoenas from the California and Texas litigation, Dey's Manager of Sales Operations, Cynthia Collie, prepared four banker's boxes of documents, some of which related to marketing of the spread. The bates ranges covered by the boxes comprised of DL-TX 0096540 through 0100303, 0100564 through 0104152, and 0105048 through 0106572. (Henderson Ex. 56, at 76:3 - 77:18.)

Dey's Response: Dey disputes US-SOF No. 167 because it is not limited to the drugs at issue in this case and because it is irrelevant and immaterial to the issues before the Court. Dey further disputes US-SOF No. 167 because it provides an incomplete, and therefore inaccurate, description of the relevant facts and because it mischaracterizes the testimony of Ms. Collie.

Dey does not dispute that the bates ranges covered by the four boxes referenced in US-SOF No. 167 are comprised of DL-TX 0096540 through 0100303, 0100564 through 0104152, and 0105048 through 0106572.

Dey disputes the remaining statements contained in US-SOF No. 167. First, Dey disputes Plaintiffs' attempt to make it seem as though Ms. Collie did not search or produce

documents from her personal files (which were ultimately put into four bankers boxes upon her resignation in May 2001) in response to the subpoenas.

Ms. Collie testified that she was provided with an excerpt from each of the subpoenas involved in the federal, California and Texas investigations, and was told to search for responsive documents, which she did. (Reid Decl., Ex. 329, Collie Dep. 66:8-17, 67:7-68:14). Ms. Collie searched her files for documents in connection with government investigations on at least three separate occasions from fall of 1997 through the date of her resignation in May 2001. (Reid Decl., Ex. 329, Collie Dep. 64:3-66:23). Specifically, Ms. Collie testified:

> A. I don't recall the dates, but to the best of my recollection there were subpoenas from the State of Texas and from the State of California where I participated in document collection.
>
> Q. So is it your testimony that you recall at least two events, two investigations, one in response to the State of Texas and a second one in response to the State of California –
>
> A. Yes.
>
> Q. --in addition to the federal investigation in 1997?
>
> A. Yes.
>
> Q: Okay. So apart from the event where you looked through your files upon resignation, you can now recall three discrete time periods where you reviewed your files and looked for documents responsive to a governmental investigation?
>
> A. Yes.
>
> Q. One by the federal government in 1997, a second one by the State of Texas and a third one by the State of California?
>
> A. Yes.

(Reid Decl., Ex. 329, Collie Dep. 65:21-66:17)

Ms. Collie testified that she made a good faith effort to search her files and gather documents that may have been responsive to the government subpoenas that Dey received:

> Q. At the time that you were asked to gather documents for the subpoena[s] -- the various subpoenas that were received by Dey from various governmental agencies, did you make a genuine and honest effort to produce documents that were responsive to those subpoenas?
>
> A. Yes.
>
> Q. Okay. And did you make a genuine and honest effort to produce documents that were within the date range and subject matter scope of those requests?
>
> A. Yes.
>
> Q. And did you have the feeling that Pam Marrs was encouraging you to do that?
>
> A. Yes.

(Reid Decl., Ex. 329, Collie Dep. 250:8-21).

At the time of her resignation in May 2001, Ms. Collie had "four lateral file drawers of files." (Reid Decl., Ex. 329, Collie Dep. 62:7-18). She placed portions of those files into four bankers boxes pursuant to Pam Marrs' request:

> A. I had a discussion with Pam Marrs, and she had requested that prior to my leaving, if there was anything that could possibly be construed to be connected with any of the subpoena requests we had received, to place it in a box and give to her.
>
> I cleaned out files, things that were seminars I had attended, different things like that. I kept a lot of files. So there were things that were not relevant to anyone but me particularly, and since I was leaving, they were no longer relevant at all. I threw those files away.
>
> But all of my files from national sales meetings, from marketing product launches and things of that nature I put in a file. And the reason that I may not have provided those documents under a subpoena request is because they would have been outside the specific date range of the subpoena request.

(Reid Decl., Ex. 329, Collie Dep. 63:5-21).

Upon her resignation in May 2001, Ms. Collie delivered the four bankers boxes to Pam Marrs. (Reid Decl., Ex. 329, Collie Dep. 71:18-21).

168. Before she left her employment at Dey in May 2001, Ms. Collie had a conversation with Dey's Vice President of Sales and Marketing Robert Mozak about the documents in her boxes. Ms. Collie testified to the following:

> Q. (By Mr. Winter) Prior to delivering those four boxes of documents to Ms. Marrs, did you have any conversations with Bob Mozak as to what should be done with your four boxes of documents?
> A. I did.
> Q. And what did Mr. Mozak tell you?
> A. He asked me to shred anything I had in my possession.

(*id.*, at p. 72:1 - 72:8; see also, *id.*, at 20:18.)

Dey's Response: Dey disputes US-SOF No. 168 because it is not related specifically to the drugs at issue and because it is irrelevant and immaterial to the issues before the Court. Dey also disputes US-SOF No. 158 because it mischaracterizes the testimony of Ms. Collie and is contradicted by other testimony in this action.

Dey disputes that Ms. Collie had a conversation with Robert Mozak about any specific documents or the content of the four bankers boxes she provided to Pam Marrs upon her resignation. (Reid Decl., Ex. 329, Collie Dep. 186:20-188:4; Ex. 344, 3/13/03 Mozak Dep. 797:6-798:3). Mr. Mozak testified that he never had any discussion with Ms. Collie about her documents or files upon her resignation:

> Q. And do you recall having any conversations with Ms. Daulong at or – or shortly before she left the company regarding production of documents in response to the ongoing Federal investigation?
>
> A. I did not speak to her about documents at all at the time she left the company.
>
> Q. Did you speak to her about documents at all at any time?

A. No. As a matter of fact, I didn't.

Q. Okay. Ms. Daulong has testified that she had – did have a conversation with you about documents that she had in her office immediately before leaving the company.

Are you aware that she so testified?

A. Yes, I am.

Q. Are you aware that Ms. Daulong has testified under oath that you directed her to shred the documents that she had maintained in her office?

A. Well, I read that, yes, and I – I don't know how she could have said that because I never talked to her about shredding documents. I never talked to her about her documents, period, much less shredding them.

(Reid Decl., Ex. 344, 3/13/03 Mozak Dep. 797:6-798:3).

Moreover, Ms. Collie testified that she did not tell Mr. Mozak that she had documents related to the spread or related to the issues in the lawsuit. (Reid Decl., Ex. 329, Collie Dep. 187:9-16). Nor did Ms. Collie have any discussion with Mr. Mozak about specific files in her office – which were files that Ms. Collie testified that she had searched in response to the subpoenas on at least three separate occasions prior to her meeting with Mr. Mozak. (Reid Decl., Ex. 329, Collie Dep. 187:5-22, 64:3-66:23). Specifically, Ms. Collie testified:

Q. Okay. Now, you didn't have an argument with Mr. Mozak after you told him you were not going to dispose of your records, did you?

A. No.

Q. And you didn't say to Mr. Mozak, Mr. Mozak, there are documents related to spread or related to the issues that the subpoena covered or related to the lawsuit? You didn't say that to Mr. Mozak, did you?

A. No.

Q. And you didn't say, What should I do with those documents that relate to the lawsuit?

A. No.

> Q. Okay. You had a lot of documents in your office, and you simply said, What should I do with all the documents in my office, and Mr. Mozak said to shred them?
>
> A. I never asked him what to do with any of my documents.
>
> Q. Okay. He just volunteered that you –
>
> A. He just said, I'd like you to shred everything in your office.
>
> Q. Okay. And there was no discussion about specific items in the office or what your files had or didn't have in them?
>
> A. No.

(Reid Decl., Ex. 329, Collie Dep. 187:5-188:4).

Ms. Collie testified that she informed Mr. Mozak that she was not willing to comply with his alleged directive and she did not have any further conversations with him about the documents. (Reid Decl., Ex. 329, Collie 79:16-25). Nor did they have an argument when she allegedly told him she was not going to comply with his alleged directive. (Reid Decl., Ex. 329, Collie Dep. 187:5-8).

169. Ms. Collie refused to destroy the documents, and instead delivered them to Pamela Marrs. (Henderson Ex. 56, at 77:23 - 78:8.)

Dey's Response: Dey disputes US-SOF No. 169 because it is not related specifically to the drugs at issue and because it is irrelevant and immaterial to the issues before the Court. Dey also disputes US-SOF No. 158 because it mischaracterizes the testimony of Ms. Collie and is contradicted by other testimony in this action. Dey does not dispute that Ms. Collie turned over four bankers boxes containing documents from Ms. Collie's personal files to Pam Marrs upon her resignation.

Dey disputes, however, that Ms. Collie was told by anyone at Dey to "destroy documents." (Reid Decl., Ex. 344, 3/13/03 Mozak Dep. 797:6-798:3). As Ms. Marrs testified, Ms. Collie was aware that the company's attorneys had told Dey employees not to throw any

documents away during the pendency of the government investigations. (Reid Decl., Ex. 398, 4/16/03 Marrs Dep. 324:6-325:4).

Moreover, Ms. Collie did not inform Pam Marrs that the documents in her files at the time of her resignation were responsive to any of the government investigations. (Reid Decl., Ex. 398, 4/16/03 Marrs Dep. 324:14-25). Rather, Ms. Marrs testified that Ms. Collie was simply concerned what to do with the documents since the company's employees were told not to throw anything away because of the government investigations:

> Q. And at the time that [Collie] left Dey's employment did she come to you with a collection of documents that she had compiled over the years that she thought may have been responsive to some of these governmental investigations?
>
> A. She came to me with documents that she had in her office and didn't know what to do with before she left.
>
> Q. Now, did she tell you that she thought that some of those documents may be responsive to the government's investigations?
>
> A. No. She was just concerned about what to do with the documents.
>
> Q. She never suggested to you that she thought those documents may be responsive to the government's investigations?
>
> A. No, I don't recall that. She was concerned because she knew that we were not to throw anything away and she wanted to make sure that they were – that I knew about them and they were protected.
>
> Q. Why weren't you to throw anything away?
>
> A. Because our attorneys advised us of that.
>
> Q. Because of the government's investigations?
>
> A. Correct.

(Reid Decl., Ex. 398, 4/16/03 Marrs Dep. 324:6-325:4).

170. Robert Mozak had received copies of the HHS OIG subpoenas served on Dey and knew of the government investigation of Dey's price reporting to government agencies at the time he instructed Ms. Collie to shred her four boxes of documents. (Henderson Ex. 85, at 323:3-323:10.)

Dey's Response: Dey disputes US-SOF No. 170 because it is not related specifically to the drugs at issue and because it is irrelevant and immaterial to the issues before the Court. Dey also disputes US-SOF No. 158 because it mischaracterizes the testimony of Mr. Mozak.

Dey disputes that Mr. Mozak instructed Ms. Collie to shred four boxes of documents. (Reid Decl., Ex. 344, 3/13/03 Mozak Dep. 797:6-798:3; Ex. 329, Collie Dep. 186:20-188:4). Dey incorporates its responses to US-SOF Nos. 167-69 as if fully set forth herein.

171. Over a year later, in late January 2003, Dey produced the following documents: DL-TX-00900851-00900855 (Albuterol Pricing Strategy, discussed at ¶ 81 above); DL-TX0091106 (Cromolyn Launch Pricing Structure, discussed at ¶ 47 above); DL-TX-0091006 (Cromolyn Marketing Plan, discussed at ¶ 94 above); DL-TX-0090967 (Cromolyn Abridged Marketing Plan, discussed at ¶ 96 above); DL-TX-0090875 (AWP Reimbursement handout at the 1995 National Sales Meeting, discussed at ¶ 112 above (Exhibit Hill 10); and DL-TX0091109 (Memorandum to sales personnel on Reimbursement Comparison Worksheet, discussed above in paragraph 119.) (Henderson Ex. 86.)

Dey's Response: Dey disputes US-SOF No. 171 because it is irrelevant and immaterial to the issues before the Court. Dey disputes the implication that the above-referenced documents were contained in the four bankers boxes that Ms. Collie provided to Pam Marrs upon Ms. Collie's resignation in May 2001. Dey also disputes that the above-referenced documents were located prior to their production in January 2003 and Plaintiffs have provided no evidence to suggest otherwise.

None of the documents referenced above were contained in the four boxes that Ms. Collie provided to Pam Marrs upon Ms. Collie's resignation in May 2001. Indeed, the bates-numbers of the above-referenced documents do not correspond to the bates-ranges that Plaintiffs have identified as constituting the ranges for the Collie boxes. With respect to DL-TX-00900851-00900855 (Albuterol Pricing Strategy), Ms. Marrs testified that the document was first located by Dey's attorneys in January 2003 in a cabinet outside of Mr. Rice's office. (Reid Decl., Ex. 398, 4/16/03 Marrs Dep. 393:10-394:5, 401:12-402:18).

172. On or about February 4, 2003, Dey produced the following documents: DL-TX0093357 (Albuterol Marketing Plan, discussed above in ¶¶ 129-132.), and DL-TX-0092981 (Ipratropium Launch Plan, discussed in ¶¶ 136-139 above). (Henderson Ex. 86A.)

Dey's Response: Dey disputes US-SOF No. 172 because it is irrelevant and immaterial to the issues before the Court.

Dey disputes the implication that the above-referenced documents were contained in the four bankers boxes that Ms. Collie provided to Pam Marrs upon Ms. Collie's resignation in May 2001. Dey incorporates its responses to US-SOF Nos. 167-171 as if fully set forth herein.

173. On or about February 13, 2003, Dey produced the document DL-TX-0096741 (1995 National Sales Meeting handout, discussed at ¶ 108 above). (Henderson Ex. 87.)

Dey's Response: Dey disputes US-SOF No. 173. Rather, DL-TX-0096741 is not a handout from the 1995 national sales meeting, but is rather a five page itinerary that sets forth "housekeeping arrangements" for the 1995 national sales meeting, including golf tee times and the attendee lists for other recreational activities and for the three workshops referred to in US-SOF No. 109.

174. On or about February 18, 2003, Dey produced the documents in the banker's boxes that Mr. Mozak had told Ms. Collie to shred, bates ranges DL-TX-0096540 through DL-TX-0100303 (box No. 1);DL-TX-0100564 through DL-TX-0104152 (box no. 2); and bates range DL-TX-0105048 through DL-TX-0106572 (box no. 3). (Henderson Ex. 56, at p. 76.)

Dey's Response: Dey disputes US-SOF No. 174 because it is irrelevant and immaterial to the issues before the Court. Dey also disputes US-SOF No. 174 because it mischaracterizes the testimony of Ms. Collie and is contradicted by other testimony and documents in this action.

Dey does not dispute that it produced four bankers boxes of documents consisting of Ms. Collie's files on February 18, 2003. Dey disputes that Mr. Mozak told Ms. Collie to shred the contents of the boxes. (Reid Decl., Ex. 344, 3/13/03 Mozak Dep. 797:6-798:3). In fact, Mr.

Mozak testified that he never had any conversation with Ms. Collie about her documents. (Reid Decl., Ex. 344, 3/13/03 Mozak Dep. 797:6-798:3).

Dey also disputes that these four boxes of documents contained documents deliberately not produced. Ms. Collie testified that she searched her files – which ultimately ended up in the four bankers boxes – on at least three separate occasions from the fall of 1997 until her resignation in May 2001 and provided what she believed was responsive for production. (Reid Decl., Ex. 329, Collie Dep. 62:7-66:23, 71:18-21).

175. On or about April 28, 2003, Dey produced to the Document Control Sheet evidencing formal approval by Mr. Mozak and Mr. Rice of the Reimbursement Comparison Worksheet (discussed at ¶ 120 above). (Henderson Ex. 88; Henderson Ex. 89.). This document was also produced from one of the four banker's boxes Mr. Mozak attempted to have destroyed.

Dey's Response: Dey disputes US-SOF No. 175 because it is irrelevant and immaterial to the issues before the Court. Dey also disputes US-SOF No. 175 because it mischaracterizes the testimony of Ms. Collie and is contradicted by other testimony and documents in this action.

Dey disputes that the Document Control Sheet set forth in Exhibit 88 to the Henderson Declaration was produced from one of the four bankers boxes that Ms. Collie provided to Pam Marrs upon Ms. Collie's resignation. Indeed, Plaintiffs cite no support for this allegation and a review of the contents of the bates-ranges covered by the four bankers boxes indicates that the Document Control Sheet did not come from the bankers boxes.

Exhibit 89 is the April 28, 2003 cover letter that accompanied the production of Henderson Exhibit 88. Exhibit 89 provides, in relevant, part: "The documents bates numbered DL-TX-0170961 through DL-TX-0170972 are documents that we recently received." (Henderson Ex. 89). By Plaintiffs' own assertion set forth in US-SOF No. 174, the Collie boxes were produced more than two months earlier on February 18, 2003. (US- SOF No. 174).

Plaintiffs have cited no evidence to demonstrate that Henderson Exhibit 88 was located prior to its production on April 28, 2003.

176. On or about May 15, 2000, Dey received a letter from Congressman Tom Bliley, Chairman of the House Committee on Commerce. (Henderson Ex. 90.) The letter stated in part:

> During the course of its investigation, the Committee also has learned some troubling information that may suggest why at least some of these substantial price variations are occurring with respect to Medicare-covered drugs. It appears that certain manufacturers may be inflating Medicare drug reimbursement rates as set by the AWP in order to help them better market their drugs. By establishing the AWP for Medicare-covered drugs at prices far above what doctors or other providers are actually charged, manufactures create a "spread." The spread is defined as the difference between the Medicare reimbursement price (95 percent of AWP) and the actual cost to doctors. Because providers can keep the spread, they thus have a monetary incentive to prescribe or utilize drugs with larger spreads. Likewise, the manufacturers of these drugs have an incentive to manipulate the AWP in order to increase spreads, and thus improve their competitiveness and sales of their drugs. In fact, the Committee has learned information indicating that some companies may have increased the spread on certain drugs in a calculated and deliberate effort to use this Medicare-funded windfall as a marketing tool to induce medical providers to use their drugs, and thereby enable themselves to gain additional market share in the sale of their products.
>
> If true, such actions would not only result in the Medicare program paying far more for certain drugs than the average wholesale price, but also cause Medicare beneficiaries to pay more out of there pockets for Medicare-covered drugs and biologicals, since they are responsible for co-payment charges tied to the AWP as well. Such outcomes clearly would be unacceptable and, as Chairman of the Committee charged with oversight of certain aspects of the Medicare program. I intend to find out whether the Medicare program and our Nation's senior citizens are being financially gouged for certain drugs. I will not tolerate taxpayers and Medicare beneficiaries being forced to subsidize the efforts of certain drug manufacturers to increase their sales. If drug manufacturers are deliberately gaming the setting of reimbursement rates for such purposes, I firmly believe that they should be exposed and held fully accountable.

(*Id.*, at 2)

Dey's Response: Dey disputes US-SOF No. 176 because it provides a selective and incomplete version of the relevant facts and because it is immaterial to the issues before the Court. Dey notes that Charles Rice responded to Mr. Bliley's letter on June 30, 2000. (Reid Decl., Ex. 399). Mr. Rice's letter provides, in relevant part:

> We are responding to your request for documents with regard to prices charged for prescription drugs marketed by Dey, L.P. and are in the process of producing those documents. Should you or your staff require explanations pertaining to any of these documents, we stand ready to meet with you for that purpose.
>
> We also stand ready to assist in any way we can to help in the resolution of the decades-old question of creation of an appropriate reimbursement system. The system needs to be one which adequately serves the patient population most in need of prescription drugs without penalizing any other participant in the process. These other participants include those involved in the development, manufacturing, and distribution of vitally important products and especially those health care providers and care givers who fulfill the government's mandate to see that those in need receive these products the same as anyone else.
>
> We offer the following information in anticipation that the Commerce Committee, and all other interested parties, will give fair and balanced consideration to all of both the evidence and the policy issues concerning this matter. The factual record here is extensive. Yet some of the proposals being offered for corrective action strike at the very core of the free market dynamics which are elements necessary for making a reimbursement system which works for all involved. All who are knowledgeable about these matters agree that changes are necessary. I certainly agree with your concerns expressed in a recent press release about a "quick fix" not working in anyone's best interest and especially not in the interests of the patients which our national health care programs are intended to serve and protect.
>
> * * *
>
> [F]or over thirty years, and certainly at the time the government now acknowledges it made its decision to rely on AWP for reimbursement purposes, the public record has been filled with evidence of the nature of AWP and the indisputable fact that it is not representative of any actual market price. In fact, pharmaceutical manufacturers do not have the

> expertise to conduct customer pricing surveys to determine actual prices, nor should they, as we understand the law, be doing so as a regular practice under the antitrust laws.
>
> Some state regulators when discussing the OIG surveys have specifically said that broader issues of adequacy of reimbursement need to be addressed to assure that prescription drugs are as readily available to those served by government programs as to others. See, for example, Reply of C. Robin Britt, Sr., Secretary of the North Carolina Department of Human Resources, to the OIG dated July 1, 1996: "We have recognized the problems that arise from balancing the appropriate EAC against assuring adequate access to providers by the recipient." Likewise, Florida regulators in responding to the 1995 OIG study stated: "Restricting reimbursement to actual cost might have the unintended effect of discouraging purchase of promotional products and eventually shifting the market to single-source products which are universally much more costly.
>
> It is clear that the best solution to the perceived problem of AWP-based reimbursement in the Medicare program lies in a full dialog among the interested parties. Those parties include representatives of regulatory agencies, pharmacies and other health-care providers, pharmaceutical manufacturers, and the indigent and elderly whom these programs serve. The purpose of this dialog is to find a politically acceptable reimbursement system which controls costs but does not disfavor purchase of any products (including generics which have done so much to reduce drug costs) or create an unlevel playing field for any product. It is also vitally important that the reimbursement system not disincentivize pharmacists and other health-care providers from serving those whom Medicare is designed to assist.

(Reid Decl., Ex. 399 at 1, 4-5 (footnotes omitted)).

177. On May 5, 2003, the HHS OIG published OIG Compliance Program Guidance For Pharmaceutical Manufacturers. (Henderson Ex. 91 (68 Fed. Reg. 23731 (May 5, 2003)).) The Guidance states in part:

> Many federal and state healthcare programs establish or ultimately determine reimbursement rates for pharmaceuticals either prospectively or retroactively. Using price and sales data directly or indirectly furnished by pharmaceutical manufacturers, the government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent or misleading information is actionable.

* * *

> Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced price services, grants for other price concessions or similar benefits offered to some or all purchasers.

(Henderson Ex. 91, at 23733-34.)

Dey's Response: Dey disputes US-SOF No. 177 because it provides a selective and incomplete version of the relevant facts and because it is immaterial to the issues before the Court. When Dey's corporate designee was asked about this passage, she testified that:

> Q. And when you became aware of this document, were you aware of this language here?
>
> A. I mean, it's always been our practice to report prices accurately as we understood the requirements.
>
> Q. Are Dey's AWPs that it reports for – for its generic drugs – do they take into account price reductions, cash discounts, free goods, rebates, and other price concessions?
>
> A. No, they don't because it says, "Where appropriate." And it's not our understanding that it's appropriate for AWP.

(Reid Decl., Ex. 346, 10/2/08 Dey Dep. 661:11-22).

178. Dey did not contact any State Medicaid agencies or federal Medicare officials to find out if it was appropriate to report inflated prices. (Henderson Ex. 10, at 28-29.)

Dey's Response: Dey disputes US-SOF No. 178 because it mischaracterizes the testimony of Mr. Johnston and is contrary to other testimony and documents in this action. Dey sent numerous price notification letters addressed to "State Medicaid Administrator" and signed by Robert F. Mozak, Dey's Executive Vice President for Sales and Marketing, informing state Medicaid administrators of Dey's WAC or AWP prices for new products and subsequent changes to those prices. (*See* Dey-SOF No. 148 (*citing* 1/4/1999 Letter, DL-0050063; 3/16/1999 Letter, DL-0050171; 3/16/1999 Letter, DEY-MDL-0105073; 8/10/1999 Letter, DEY-LABS-

0415389; 3/28/2000 Letter, DEY-LABS-0415614; 7/18/2000 Letter, DL-0050107; 7/18/2000 Letter, DEY-BO0018899; 8/2/2000 Letter, DEY-LABS-0415537; 1/2/2001 Letter, DEY-BO0018909; 6/2001 Letter, DEY-BO-0246811; 10/2001 Letter, DEY-BO-0254353; 12/2001 Letter, DEY-MDL-0105071; 1/2002 Letter, EDEY-BO-0053142)).

Furthermore, multiple states have produced similar letters which they received from Dey, such as Alabama, Connecticut, Illinois, Maryland, Texas, Virginia, and Wisconsin. (*See* Dey-SOF No. 150 (*citing* Alabama: 2/22/2006 Letter, ALMED-357604; Connecticut: 12/15/2003 Letter, CT0024785; Illinois: 9/2008 Letter, AWP-IL-00024760; Maryland: 3/2003 Letter, MD0015270; Texas: 3/16/1999 Letter, R1-014879, 8/10/1999 Letter, R1-014889, 3/31/2000 Letter, R1-014902, 7/18/2000 Letter, R1-014883; Virginia: October 2004 Letter, VA_000001648; Wisconsin: 3/16/1999 Letter, WI-Prod-AWP-128277, 8/10/1999 Letter, WI-Prod-AWP-128276, 3/28/2000 Letter, WI-Prod-AWP-128871, 3/31/2000 Letter, WI-Prod-AWP-128273, 7/18/2000 Letter, WI-Prod-AWP-128269, 1/2/2001 Letter, WI-Prod-AWP-128245, 12/2001 Letter, WI-Prod-AWP-128225, 9/2002 Letter, WI-Prod-AWP-128869). *See also* Dey-SOF Nos. 156-157).

For example, in one such letter dated August 10, 1999, Mr. Mozak wrote to state Medicaid administrators as well as regional Medicare benefits administrators, apprising them of a new NDC number for Dey's Albuterol Sulfate Inhalation Solution 0.5%. (8/10/1999 Letter, DEY-LABS-0415389.) The letter describes Dey's WAC as follows:

> As you know, WAC is referred to by data reporting services and government agencies as an "estimate," and Dey believes that WAC generally means the <u>invoice</u> price charged by a pharmaceutical manufacturer to drug wholesalers. As you also know, WAC does <u>not</u> include the net effect of discounts from invoice price (based on volume of purchases, speed of payment and other factors), rebates, chargebacks, administration fees and other such cost adjustments which are well-known and commonplace in the pharmaceutical

> industry and can affect, to a greater or lesser degree, the actual "final" cost to each purchaser. These discounts may not be determined until some months after the date of invoice. Therefore, we remind you that WAC may well not be representative of actual market costs to those entities which you are reimbursing under Medicaid. (8/10/1999 Letter, DEY-LABS-0415389) (emphasis in original).

The letter goes on to describe AWP as follows:

> Further, as you also know, the Average Wholesale Price (or "AWP") per unit listed above does not represent actual wholesale prices which will be charged or paid for this product. It is Dey's practice to set an AWP before a product is first sold and not subsequently to change that figure. We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators. (8/10/1999 Letter, DEY-LABS-0415389) (emphasis in original).

(*See* Dey-SOF Nos. 151-155).

179. Dey never contacted any Medicare carrier to ask whether it was permissible to report and cause to be published average wholesale prices that were higher than actual market prices. (*Id.*, at p. 28.)

Dey's Response: Dey disputes US-SOF No. 179 because it mischaracterizes the testimony of Mr. Johnston and is contrary to other documents and testimony in this action. Dey sent letters that contained similar language to those cited in paragraph 178 above to Medicare Durable Medical Equipment Regional Carriers ("DMERCs"). (*See* Dey-SOF No. 149 (*citing* 8/10/1999 Letter, DEY-LABS-0415389, at DEY-LABS-0415397)). Furthermore, Carolyn Helton of CIGNA, one of the DMERCs, recalled receiving such price notification letters from Dey. (*See* Dey-SOF No. 158 (*citing* 3/13/2008 Helton Dep. 117:1-8)).

180. On April 4, 2008, the United States served upon Dey a Notice of Deposition pursuant to Fed. R. Civ. P. 30(b)(6), which listed topics of inquiry that included the following:

> 6. With regard to the plaintiffs' claim in the Complaint (at ¶ 50) that Dey made false or fraudulent representations about drug prices and costs to RedBook, First DataBank, and Medispan, the factual basis for the statement in Dey's Thirteenth Defense that, "As to any statement asserted against Dey that Plaintiff allege

[sic] to be false or misleading, Dey had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading." This topic shall include but not be limited to:

a. The identity of each employee (current and former) of Dey who held a belief that Dey's price representations were not false or fraudulent;
b. The time period when such person held that belief;
c. Each communication and the identity of each document relied upon, considered or used by the person in forming the belief;
d. All other information that formed a basis for the belief.

8. Dey's belief, if any, that the United States government (or any agency or agent thereof) approved of or acquiesced in Dey's practice of causing the publication of AWPs for Dey products that were higher than actual average wholesale prices or WACs that were higher than actual wholesale acquisition costs, including:

a. The identity of each employee (current and former) of Dey who held such a belief;
b. The time period when such person held that belief;
c. Each communication and the identity of each document relied upon, considered or used by the person in forming the belief;
d. All other information that formed a basis for the person's belief.

(Henderson Ex. 92.)

Dey's Response: Dey disputes US-SOF No. 180 because it is immaterial to the issues before the Court.

181. Dey designated Dey employee Pamela Marrs to testify on behalf of the Company regarding these topics, among others. With regard to Topic #6 above, Ms. Marrs produced two binders containing numerous government reports, plus a letter from Dey President Charles Rice to the Hon. Thomas Bliley, marked as deposition Exhibits 33A, 33B, and 33C, respectively (collectively "Exhibit 33"). (Henderson Ex. 21, at 509-510.)

Dey's Response: Dey does not dispute that Ms. Marrs, in 2008, some eleven years after this complaint was first filed sealed, and as virtually the sole senior remaining Dey employee who had been present in the 1990s, was designated to respond to this topic over the course of the

three days of testimony that she has given as a corporate designee in this case. Dey disputes US-SOF No. 181 because it is immaterial to the issues before the Court.

182. The materials in Exhibit 33 were compiled by Dey's lawyers. (Henderson Ex. 21, at 533:21 - 534:16.)

Dey's Response: Dey does not dispute that Exhibit 33 was compiled, as required by Fed. R. Civ. P. 30(b)(6), to educate the witness on this topic. Dey also states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees from the relevant time period had already left the company. Dey also disputes US-SOF No. 182 because it is immaterial to the issues before the Court.

183. In preparation for the deposition, Ms. Marrs did not talk to anyone at Dey concerning Topic #6 other than counsel. (*Id.*, at 521:21 - 522:8.)

Dey's Response: Dey states that it fully complied with its duties under Fed. R. Civ. P. 30(b)(6) in designating and educating a corporate designee on this topic. Dey also states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees from the relevant time period had already left the company. Dey also disputes US-SOF No. 183 because it is immaterial to the issues before the Court.

184. Ms. Marrs testified that she had spoken previously to Mr. Mozak about the topic prior to 2002 and "early on in the litigation." (*Id.*, at 517:5-16.) Mr. Mozak did not say he had read any of the reports. (*Id.*, at 517 - 518). Ms. Marrs testified " what he knew or didn't know about these other reports prior to that time, I'm not aware. You'd have to ask him." (*Id.*, at 518:10 - 519:22.)

Dey's Response: Dey states that it fully complied with its duties under Fed. R. Civ. P. 30(b)(6) in designating and educating a corporate designee on this topic. Dey also states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees, including Mr. Mozak, from the relevant time period had already left the company. Plaintiffs were free to, but chose not to, depose Mr. Mozak

to inquire further into this topic. Dey also disputes US-SOF No. 184 because it is immaterial to the issues before the Court.

185. When asked who at Dey held a belief that the government approved of Dey's reporting of inflated prices, Ms. Marrs answered:

> THE WITNESS: Well, if it's really the same people, it's Bob Mozak. It's whoever else had the knowledge from the attorneys of these various government reports as well as -- and I don't know other than Mozak to list names, quite frankly. I suspect Russ Johnston is probably aware of all these government publications, but I haven't specifically spoken with him about it, so it's hard for me to name anyone other than Bob.

(*Id.* at 528:15 - 528:1.)

Dey's Response: Dey states that it fully complied with its duties under Fed. R. Civ. P. 30(b)(6) in designating and educating a corporate designee on this topic. Dey also states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees, including Mr. Mozak, from the relevant time period had already left the company. Plaintiffs were free to, but chose not to, depose Mr. Mozak to inquire further into this topic. Dey also notes that, starting in 1999, it sent price notification letters on a regular basis to state Medicaid offices and to the federal DMERCs informing them exactly what Dey's AWPs and WACs represented. (*See* Dey-SOF Nos. 148-158). State Medicaid officials repeatedly testified that they were unaware of any contact initiated by their agencies to Dey after Dey sent such letters. (*See* Dey-SOF No. 157). Dey also disputes US-SOF No. 185 because it is immaterial to the issues before the Court.

186. Ms. Marrs testified that there is nobody at Dey who is more knowledgeable about the government reports in Deposition Exhibit 33 than she. (*Id.*, at 530:9-12.)

Dey's Response: Dey states that it fully complied with its duties under Fed. R. Civ. P. 30(b)(6) in designating and educating a corporate designee on this topic. Dey also states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed

sealed and years after many of Dey's employees, including Mr. Mozak, from the relevant time period had already left the company. Plaintiffs were free to, but chose not to, depose other employees from the relevant time period, to inquire further into this topic. Dey also disputes US-SOF No. 186 because it is immaterial to the issues before the Court.

187. At the time of the deposition, Ms. Marrs had not read any of the reports in Deposition Exhibit 33 in its entirety. (*Id.*, at 530:17-22.)

Dey's Response: Dey states that it fully complied with its duties under Fed. R. Civ. P. 30(b)(6) in designating and educating a corporate designee on this topic. Dey also states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees from the relevant time period had already left the company. Dey also disputes US-SOF No. 187 because it is immaterial to the issues before the Court.

188. Dey is not aware of anyone else at Dey who has read any of the government reports in Deposition Exhibit 33. (*Id.*, at 531.)

Dey's Response: Dey states that it fully complied with its duties under Fed. R. Civ. P. 30(b)(6) in designating and educating a corporate designee on this topic. Dey also states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees from the relevant time period had already left the company. Plaintiffs were free to, but chose not to, depose other employees from the relevant time period to inquire further into this topic. Dey also disputes US-SOF No. 188 because it is immaterial to the issues before the Court.

189. Dey does not know when any Dey employee might have read any of the government reports in Deposition Exhibit 33. (*Id.*, at 532:6-13.)

Dey's Response: Dey states that it fully complied with its duties under Fed. R. Civ. P. 30(b)(6) in designating and educating a corporate designee on this topic. Dey also states that

Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees from the relevant time period had already left the company. Plaintiffs were free to, but chose not to, depose other employees from the relevant time period to inquire further into this topic. Dey also disputes US-SOF No. 189 because it is immaterial to the issues before the Court.

190. The United States' Rule 30(b)(6) notice to Dey included the following Topic #10:

> Dey's belief, if any, that the United States government (or any agency or agent thereof) approved of or acquiesced in Dey causing the Medicare program to reimburse providers for Dey drugs in amounts significantly in excess of provider acquisition costs plus any established dispensing fee, including:
> a. The identity of each employee (current and former) of Dey who held such a belief,
> b. The time period when such person held that belief;
> c. Each communication and the identity of each document relied upon, considered or used by the person in forming the belief;
> d. All other information that formed a basis for the person's belief.

(Henderson Ex. 92.)

Dey's Response: Dey disputes US-SOF No. 190 because it is immaterial to the issues before the Court.

191. In response to Topic #10(a), Ms. Marrs testified that Mr. Mozak and Mr. Russell Johnston held the belief that the government approved of Dey's price reporting practices. (Henderson Ex. 61, at 628-631, 633-634.)

Dey's Response: Dey states that it fully complied with its duties under Fed. R. Civ. P. 30(b)(6) in designating and educating a corporate designee on this topic. Dey also states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees from the relevant time period had already left the company. Plaintiffs were free to, but chose not to, depose other employees from the relevant time period to inquire further into this topic. Dey also notes that, starting in 1999, it sent price

notification letters on a regular basis to state Medicaid offices and to the federal DMERCs informing them exactly what Dey's AWPs and WACs represented. (*See* Dey-SOF Nos. 148-158). State Medicaid officials repeatedly testified that they were unaware of any contact initiated by their agencies to Dey after Dey sent such letters. (*See* Dey-SOF No. 157). Dey also disputes US-SOF No. 191 because it is immaterial to the issues before the Court.

192. With regard to Topic No. 10.c, Ms. Marrs testified that she did not prepare on this topic. (*Id.*, at 632:2-12.)

Dey's Response: Dey states that it fully complied with its duties under Fed. R. Civ. P. 30(b)(6) in designating and educating a corporate designee on this topic. Dey also states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees from the relevant time period had already left the company. Plaintiffs were free to, but chose not to, depose other employees from the relevant time period to inquire further into this topic. Dey also disputes US-SOF No. 192 because it is immaterial to the issues before the Court.

193. With regard to Topic No. 10.c, Ms. Marrs testified that she did not know what documents informed Mr. Mozak in his belief. (*Id.*, at 635-636.)

Dey's Response: Dey states that it fully complied with its duties under Fed. R. Civ. P. 30(b)(6) in designating and educating a corporate designee on this topic. Dey also states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees from the relevant time period had already left the company. Plaintiffs were free to, but chose not to, depose Mr. Mozak to inquire further into this topic. Dey also disputes US-SOF No. 193 because it is immaterial to the issues before the Court.

194. Ms. Marrs testified that Russell Johnston believed that the government knew and approved of Dey's price reporting practices. (*Id.*, at 636:19 - 638:7.)

Dey's Response: Dey states that it fully complied with its duties under Fed. R. Civ. P. 30(b)(6) in designating and educating a corporate designee on this topic. Dey also states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees from the relevant time period had already left the company. Plaintiffs were free to inquire further into this topic at Mr. Johnston's deposition, which was held on December 10-11, 2008. Dey also notes that, starting in 1999, it sent price notification letters on a regular basis to state Medicaid offices and to the federal DMERCs, a number of which were signed by Mr. Johnston, informing them exactly what Dey's AWPs and WACs represented. (*See* Dey-SOF Nos. 148-158). State Medicaid officials repeatedly testified that they were unaware of any contact initiated by their agencies to Dey after Dey sent such letters. (*See* Dey-SOF No. 157). Dey also disputes US-SOF No. 194 because it is immaterial to the issues before the Court.

195. Ms. Marrs testified that she holds the belief that the government knew and approved of Dey's price reporting practices. (*id.*, at 638:12 - 639:18.)

Dey's Response: Dey disputes US-SOF No. 195 because it is unsupported by the testimony cited. Dey also notes that, starting in 1999, it sent price notification letters on a regular basis to state Medicaid offices and to the federal DMERCs informing them exactly what Dey's AWPs and WACs represented. (*See* Dey-SOF Nos. 148-158). State Medicaid officials repeatedly testified that they were unaware of any contact initiated by their agencies to Dey after Dey sent such letters. (*See* Dey-SOF No. 157). Dey also disputes US-SOF No. 195 because it is immaterial to the issues before the Court.

196. Ms. Marrs testified that her belief was based on communications with counsel. She declined to disclose the content of her communications with counsel. (*Id.*, at 638:12 - 639:18.)

Dey's Response: Dey disputes US-SOF No. 196 because it is vague and unsupported by the testimony cited to the extent it references any "belief" held by Ms. Marrs. Dey disputes US-SOF No. 196 because it is immaterial to the issues before the Court. Dey incorporates its response to US-SOF No. 195 as if fully set forth herein.

197. After the Rule 30(b)(6) deposition, Russell Johnston testified that he has not read any OIG reports, and has no understanding one way or the other whether the federal government has approved of Dey's price reporting practice. (Henderson Ex. 10, at 26-27.)

Dey's Response: Dey disputes US-SOF No. 197 because it is incomplete and therefore misleading. Dey further states that, starting in 1999, it sent price notification letters, a number of which were signed by Mr. Johnston, on a regular basis to state Medicaid offices and to the federal DMERCs informing them exactly what Dey's AWPs and WACs represented. (*See* Dey-SOF Nos. 148-158). State Medicaid officials repeatedly testified that they were unaware of any contact initiated by their agencies to Dey after Dey sent such letters. (*See* Dey-SOF No. 157). Dey also disputes US-SOF No. 197 because it is immaterial to the issues before the Court.

198. Dey has no evidence that during the period 1994 through October 1997 (when the first OIG subpoena was served) that any Dey employee read or was aware of any government report concerning AWP or WAC prices. (Henderson Ex. 21, at 521-532; Henderson Ex. 61, at 632-639.)

Dey's Response: Dey disputes US-SOF No. 198. Dey states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees from the relevant time period had already left the company. Plaintiffs were free to, but chose not to, depose other employees from the relevant time period to inquire further into this topic. Dey also disputes US-SOF No. 198 because it is immaterial to the issues before the Court.

199. Dey has no evidence that when Dey set the AWPs and WACs for the Subject Drugs and reported those AWPs and WACs to the Publishers, Dey or any of its employees

considered or relied on any government report concerning AWP or WAC pricing. (Henderson Ex. 21, at 521-532; Henderson Ex. 61, at 632-639.)

Dey's Response: Dey disputes US-SOF No. 199. Dey states that Plaintiffs served Dey with this deposition topic eleven years after the complaint was first filed sealed and years after many of Dey's employees from the relevant time period had already left the company. Plaintiffs were free to, but chose not to, depose other employees from the relevant time period to inquire further into this topic. Dey also disputes US-SOF No. 199 because it is immaterial to the issues before the Court.

200. The Court is respectfully referred to paragraphs 1 - 16 of the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants for certain facts concerning Medicare Part B payment for DME drugs.

Dey's Response: Dey incorporates Defendants' Joint Responses to paragraphs 1-16 of the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants as if fully set forth herein.

201. During the relevant time period, Medicare Part B paid claims for ipratropium bromide inhalation solution, .02%, unit dose, when used in connection with durable medical equipment. (Henderson Common Ex. 3, ¶ 3.) There were three different HCPCS codes used to process claims for ipratropium bromide. The HCPCS code J7645 was used from January 1, 1995, through March 31, 1997. The HCPCS code K0518 applied from April 1, 1997, through December 31, 1999. The code J7644 applied from January 1, 2000, through the present. (*Id.* ¶ 16.)

Dey's Response: Dey does not dispute that the HCPCS codes set forth in US-SOF No. 201 were used by CIGNA to process claims for ipratropium bromide. The evidence cited by the Government does not support the use of the listed HCPCS codes by any other carrier or DMERC.

202. The DMERC for Region D, CIGNA Government Services, Inc. ("CIGNA"), paid on behalf of Medicare many provider claims for reimbursement for ipratropium bromide. (Henderson Ex. 63, ¶¶ 9-13 and Exhibits C and D thereto.)

Dey's Response: Dey disputes US-SOF No. 202 because it is not supported by the evidence cited.

203. CIGNA reimbursed for covered drugs at the lower of the allowable amount calculated by the carrier or the amount submitted by the provider in the claim. (Henderson Common Ex. 3, ¶ 3.)

Dey's Response: Dey disputes US-SOF No. 203. From 1992 to 1997, the Medicare ingredient reimbursement formula was the lower of (1) the billed charge from the provider, or (2) the lower of the Estimated Acquisition Cost "EAC" or the median AWP of all of the generic forms of the products in the relevant code. (Dey-SOF No. 175). According to the Medicare regulations, EAC was to be based on surveys of actual invoice prices paid by providers. (Dey-SOF No. 176). In practice, the EAC component of Medicare Part B drug reimbursement allowable was never utilized. (Dey-SOF No. 176) In addition to the ingredient cost component, CIGNA and the other carriers would reimburse a dispensing fee for covered drugs. Prior to reforms introduced in 2005 under the MMA, the dispensing fee allowed for inhalation drugs was $5.00. (Dey-SOF No. 205). Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

204. CIGNA performed drug pricing calculations using average wholesale price (AWP) data obtained from Red Book. (Henderson Common Ex. 3, ¶ 9.) In general, CIGNA performed drug pricing updates quarterly.

Dey's Response: Dey does not dispute US-SOF No. 204, but states that CIGNA used its discretion in selecting AWPs from the Red Book. Dey further adds that CMS has consistently instructed carriers to use "the AWP as reflected in sources such as the Red Book, Blue Book or Medispan" in its instructions to carriers. (*See, e.g.*, Reid Decl., Ex. 160; Reid Decl., Ex. 171; Reid Decl., Ex. 172; Reid Decl., Ex. 173; Reid Decl., Ex. 174.) Dey incorporates by reference

its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's declaration.

205. Generally, to determine the allowable fee for a particular DME drug, CIGNA used the Red Book to select the NDCs falling within the narrative description of the HCPCS code. CIGNA then created an array of prices that included the AWP for each selected NDC, using Red Book data. CIGNA converted each AWP price to a unit price, so that there was a common measure of price. (Henderson Common Ex. 3, ¶¶ 9-10.)

Dey's Response: Dey disputes US-SOF No. 205. Ms. Helton did not select all NDCs that fell within the narrative description of the HCPCS code. Carolyn Helton of CIGNA testified that she would have to use her discretion on whether to add a price for a particular code to an array. (Reid Decl., Ex. 153, 3/13/08 Helton Dep. 151:7-17). She "generally did not select drugs with special sized packaging, or convenience items such as flip-top vials, carpu-jets, tubes, and others." (Henderson Common Ex. 3, ¶ 10). Furthermore, "[t]he policy to not select such items for inclusion in arrays was developed and implemented over a period of time by DMERC representatives in consultation with HCFA officials. The restrictions now appear in CMS's Internet-Only Manual (IOM), Publication 100-04, Medicare Claims Processing Manual (Chapter 17, § 20.5.5)." (*Id*. (footnote omitted)).

The Medicare Claims Processing Manual, Chapter 17, § 20.5.5 cited by Ms. Helton states:

> To determine AWPs and Payment Allowance Limits, carriers:
>
> - Exclude special sized packaging, e.g., Institutional Use.
>
> - Do not use flip top vial, carpu-ject, tubes, cartridge, rapi-ject, lure lock syringe, blunt point abu-ject, rapi-ject, leurlock, advantage, min-i-jet, unless it is the only source available. These items are considered convenience and tend to inflate the price.

- Do not use drugs marked preservative free, sulfite free, piggy back, or sterile unless the HCPCS description specifies otherwise.

- Do not use drugs with an Orange Book Code (OBC) other than "A" if more than one source exists. This restriction applies to SADMERC only (reference CMS Memorandum PUB 60 AB.94-2, 60 dated March 1994).

(Reid Decl., Ex. 400).

Other DMERCs, such as Palmetto, followed this policy as well. (Henderson Dey Ex. 98, ¶¶ 16-17). Robin Kreush Stone, a Palmetto witness, submitted a declaration in connection with the United States' Motion for Partial Summary Judgment in which she states that she did not include certain Zenith Goldline ipratropium products in the ipratropium array she created because the product had a "P.F." label, meaning preservative free, and "Preservative Free products often utilized special packaging which tended to increase the price." (Henderson Dey Ex. 98, ¶ 17).

Many of Dey's products were preservative free and some were listed as such in the Red Book. For example, in the 1998 Red Book, Dey's 2.5 ml 30s UD is listed as "PF" or preservative free. (Henderson Ex. 97 at p. 7 of 13). Therefore, pursuant to the Medicare Claims Processing Manual, this product should have been excluded from the array.

Dey further disputes the last sentence of US-SOF No. 205 because it is not supported by the evidence cited. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

206. Using the array, CIGNA then determined the median AWP for the NDCs in the array. If there was only one NDC with a published AWP in the array, CIGNA selected that price as the median. If there was an odd number of NDCs in the array, CIGNA selected the middle price. If there was an even number of NDCs in the array, CIGNA took the average of the middle two NDC prices to achieve a median. (Henderson Common Ex. 3, ¶ 11.)

Dey's Response: Dey does not dispute that CIGNA's intent was to determine the array as described in US-SOF No. 206, however, the Government has not provided all of CIGNA's arrays for all drugs; therefore it is not possible for the Government to demonstrate that this methodology was followed in all instances. It would be necessary to examine each array individually to make the determination of whether this policy was followed in a particular instance. Furthermore, CIGNA used its discretion in selecting AWPs to include in the array. Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

207. The precise method followed by CIGNA for determining allowable reimbursement rates changed in the 1996-2003 period, in accordance with changing regulations or CMS instructions. (Henderson Common Ex. 3, ¶ 12.)

Dey's Response: Dey does not dispute US-SOF No. 207, but states that CIGNA used its discretion in selecting AWPs to include in the array. Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

208. From 1994 through December 31, 1997, CIGNA calculated the allowable reimbursement rate as 100% of the median AWP of the generic forms of the drug (unless, as indicated above, only a brand drug was available). (Henderson Common Ex. 3, ¶ 13.)

Dey's Response: Dey does not dispute that from 1994 through December 31, 1997, the DMERCs were instructed to calculate the allowable reimbursement rate as 100% of the median AWP of the generic forms of the drug unless only a brand drug was available. Without having

reviewed the arrays for CIGNA for all drugs, Dey disputes as unsupported the representation that this calculation was performed by CIGNA in all cases for all drugs without exception. Furthermore, Dey disputes that the median calculation performed by CIGNA considered all of the generic forms of a given drug, as the record demonstrates that some generic forms were specifically excluded. (Henderson Common Ex. 3, ¶ 10). Carolyn Helton of CIGNA testified that she would have to use her discretion on whether to add a price for a particular code to an array. (Reid Decl., Ex. 153, 3/13/08 Helton Dep. 151:7-17). Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

209. Beginning January 1, 1998, as a result of the Balanced Budget Act of 1997, the DMERCs began paying providers at ninety-five percent of the median AWP. Accordingly, for quarters beginning January 1998, CIGNA calculated the allowable fee by multiplying the median AWP by 0.95. (Henderson Common Ex. 3, ¶ 13.)

Dey's Response: Dey does not dispute that beginning January 1, 1998, as a result of the Balanced Budget Act of 1997, the DMERCs were instructed to begin paying providers at ninety-five percent of the median AWP. This information was transmitted to carriers and DMERCs in a Program Memoranda dated January, 1998 which states: "Effective January 1, 1998, pay for drugs and biologicals not paid on a cost or prospective payment basis at the lower of the billed charge or 95 percent of the AWP. This change in payment allowance recognizes the fact that the AWP is not a true discounted price and, therefore, does not reflect the cost to the physician or supplier furnishing the drug to the Medicare beneficiary. Part B deductible and coinsurance requirements apply." (Dey-SOF ¶ 180). Without having reviewed the arrays for all of the DMERCs and for all drugs, Dey disputes as unsupported the implication that this calculation was

performed by all DMERCs in all cases for all drugs without exception. Dey further states that CIGNA used its discretion in selecting AWPs to include in the array. Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

Dey further adds that CMS has consistently instructed carriers to use "the AWP as reflected in sources such as the Red Book, Blue Book or Medispan" in its instructions to carriers. (*See, e.g.*, Reid Decl., Ex. 160; Reid Decl., Ex. 171; Reid Decl., Ex. 172; Reid Decl., Ex. 173; Reid Decl., Ex. 174).

210. Effective approximately January 1999, HCFA issued instructions to the DMERCs that the allowable fee was to be determined as the lower of the median of the generic sources of the drug or the lowest priced brand name AWP. (Henderson Common Ex. 3, ¶ 13; Henderson Ex. 94.)

Dey's Response: Dey does not dispute that effective approximately January 1999, HCFA issued instructions to the DMERCs that the allowable fee was to be determined as the lower of the median of the generic sources of the drug or the lowest priced brand name AWP. Without having reviewed the arrays for all of the DMERCs and for all drugs, Dey disputes as unsupported the implication that this calculation was performed by all DMERCs in all cases for all drugs without exception. Dey further states that CIGNA used its discretion in selecting AWPs to include in the array. Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

211. Once CIGNA determined a new allowable fee for a HCPCS code, the new or updated price was entered into the electronic claims processing system used by the DMERCs

for paying Part B claims, referred to as the ViPS Medicare System. Once a new or updated allowable fee was entered, the ViPS Medicare System used that price for determining the reimbursement of all applicable Medicare Part B claims that had not already been processed through the pricing part of the system. (Henderson Common Ex. 3, ¶ 14.)

Dey's Response: Dey disputes US-SOF No. 211 as immaterial and irrelevant. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

212. The arrays used by CIGNA to determine the allowable amount for ipratropium bromide from the third quarter of 1996 ("1996 Q3") through 2003 Q4 are at Exhibit A to the Declaration of Carolyn Helton, the CIGNA DMERC pricing analyst. (Henderson Common Ex. 3, ¶ 16.)

Dey's Response: Dey does not dispute that the arrays attached as Exhibit A to the Declaration of Carolyn Helton purport to be CIGNA's calculation of the median price for ipratropium. Dey does dispute that the allowable amount described in US-SOF No. 212 was actually used by CIGNA for reimbursement in all cases, as the United States has admitted that a percentage of claims were paid on the provider's billed amount and that there are also outliers. (Henderson Ex. 63, ¶ 10). Dey further states that CIGNA used its discretion in selecting AWPs to include in the array. Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

213. For quarters prior to 1997 Q2, Dey's products do not appear in the array. Therefore Dey's reported prices had no impact on the amounts paid by CIGNA for ipratropium bromide for claims processed before April 1, 1997. (Henderson Common Ex. 3, ¶ 18.)

Dey's Response: Dey does not dispute that Dey's ipratropium was not included by CIGNA in the arrays prior to 1997 Q2. Dey disputes that pharmaceutical products "appear" in

the CIGNA arrays, rather, they are selected by CIGNA employees for inclusion in the arrays. (Henderson Common Ex. 3, ¶¶ 10-11). Manufacturers do not include their products in the arrays. Dey disputes the implication in the second sentence of US-SOF No. 213 that Dey's reported prices had an impact on the amounts paid by CIGNA for ipratropim bromide for claims processed after April 1, 1997. Dey further states that CIGNA used its discretion in selecting AWPs to include in the array. Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

214. For each the arrays for the quarters from 1997 Q2 through 2003 Q4, Dey's products did appear in the arrays. (Henderson Cominon Ex. 3, Exhibit A thereto.) Roxane's ipratropium bromide products also appeared in the arrays. (Henderson Common Ex. 3, ¶ 18 and Ex. A thereto.)

Dey's Response: Dey disputes US-SOF No. 214. Dey and Roxane's products do not "appear" in the CIGNA arrays from 1997 Q2 through 2003 Q4. Rather, these particular products were selected by CIGNA employees for inclusion in the arrays. (Henderson Common Ex. 3, ¶¶ 10-11). Dey and Roxane did not include their products in the arrays. Dey further states that CIGNA used its discretion in selecting AWPs to include in the array. Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

215. In the arrays for the period 2001 Q2 through 2003 Q4, Roxane's NovaPlus ipratropium bromide products (having NDCs beginning with 00054-8402) appear in the arrays as brand products. (Henderson Common Ex. 3, Exhibit A thereto.) Dey's expert Dr. David Bradford has no opinion whether the Roxane NovaPlus products were properly treated as brand products. (Henderson Ex. 95, at 409-410.)

Dey's Response: Dey disputes the first sentence of US-SOF No. 215. Pharmaceutical products do not "appear" in the CIGNA arrays, rather, they were selected by CIGNA employees for inclusion in the arrays. (Henderson Common Ex. 3, ¶¶ 10-11). Manufacturers do not include their products in the arrays. Dey does not dispute that CIGNA chose to include Roxane's NovaPlus ipratropium bromide products as brand products in the arrays for the period 2001 Q2 through 2003 Q4. Dey does not dispute the second sentence of US-SOF No. 215. Dey further states that CIGNA used its discretion in selecting AWPs to include in the array. Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

216. All of the arrays from 1997 Q2 through 2003 Q4 show the same median generic unit price, $3.52 per milligram, for K0518 and J7644. (Henderson Common Ex. 3, Exhibit A thereto. During the period 1997 Q2 through December 31, 1997, the allowable amount determined by CIGNA for K0518 and J7644 was 100 percent of the median, or $3.52 per milligram. (*Id.*)

Dey's Response: Dey does not dispute US-SOF No. 216 to the extent that it refers to the CIGNA arrays attached as Exhibit A to Henderson Common Ex. 3. However, CIGNA chose to include or exclude certain products in particular arrays, and the inclusion of those products impacts the median calculation. Dey disputes the United States' attempt to isolate the CIGNA arrays for a finding of partial summary judgment without providing the context of the actions of the other 3 DMERCs. The Government has selected the CIGNA arrays which only include Dey and Roxane's products and asks the Court to look at these arrays in isolation. However, because the various DMERCS had discretion to determine which products to include in a particular array, it is necessary to view arrays for all DMERCs together as well as the guidance given to the DMERCs in order to determine whether products were properly included

in arrays. Dey further states that CIGNA used its discretion in selecting AWPs to include in the array. Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

217. After January 1, 1998, the effective date of the Balanced Budget Act of 1997, the allowable amount determined by CIGNA for K0518 and J7644 was 95 percent of $3.52, or $3.34. (Henderson Common Ex. 3, Exhibit A thereto.)

Dey's Response: Dey does not dispute US-SOF No. 217 to the extent that it refers to the CIGNA arrays attached as Exhibit A to Henderson Common Ex. 3. However, CIGNA chose to include or exclude certain products in particular arrays, and the inclusion of those products impacts the median calculation. Dey disputes the United States' attempt to isolate the CIGNA arrays for a finding of partial summary judgment without providing the context of the actions of the other 3 DMERCs. The Government has selected the CIGNA arrays which only include Dey and Roxane's products and asks the Court to look at these arrays in isolation. However, because the various DMERCS had discretion to determine which products to include in a particular array, it is necessary to view arrays for all DMERCs together as well as the guidance given to the DMERCs in order to determine whether products were properly included in arrays. Dey further states that CIGNA used its discretion in selecting AWPs to include in the array. Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

218. For the periods 1997 Q2 through 2001 Q3, any reduction of one percent or more in the AWPs of the Dey products (whether the AWP is expressed as a unit price or as

the package price) would have lowered the median and therefore the Medicare allowed amount. (Henderson Common Ex. 3, ¶ 23.)

Dey's Response: Dey disputes US-SOF No. 218 as inadmissible pursuant to Federal Rules of Evidence 602 and 701. Dey disputes that any reduction of one percent or more in the AWPs of the "Dey products" would have lowered the median, as the arrays referenced are for ipratropium only. Dey disputes the United States' attempt to isolate the CIGNA arrays for a finding of partial summary judgment without providing the context of the actions of the other 3 DMERCs. The Government has selected the CIGNA arrays which only include Dey and Roxane's products and asks the Court to look at these arrays in isolation. However, because the various DMERCS had discretion to determine which products to include in a particular array, it is necessary to view arrays for all DMERCs together as well as the guidance given to the DMERCs in order to determine whether products were properly included in arrays. (*See, e.g.*, Reid Decl., Ex. 405 (8/28/09 Bradford Decl.) ¶¶ 11-12). Dey further states that CIGNA used its discretion in selecting AWPs to include in the array which impact the median calculation. For 15 overlapping quarters for which an Administar array is available, the Administar array differs from the CIGNA array in 8 quarters. (*See* Reid Decl., Ex. 405 (8/28/09 Bradford Decl.) ¶ 12). In those eight quarters, a 1% change in Dey's AWP would not result in a different median for these eight Administar arrays. (*See* Reid Decl., Ex. 405 (8/28/09 Bradford Decl.) ¶ 12). Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

219. For the period 1997 Q2 through 2003 Q4, any reduction of one percent or more in the AWPs of both the Dey and Roxane ipratropium bromide products would have reduced the Medicare allowed amount, regardless of whether one changes the Roxane NovaPlus prices. (Henderson Common Ex. 3, ¶ 24.)

Dey's Response: Dey disputes US-SOF No. 219 as inadmissible pursuant to Federal Rules of Evidence 602 and 701. Dey further disputes US-SOF No. 219 because it improperly considers Dey and Roxane's AWPs together. Dey has moved for summary judgment on this issue and refers the Court to pages 35-37 of Dey's Motion for Summary Judgment and Section IV C of Dey's Reply in Further Support of its Motion for Summary Judgment. Dey further states that CIGNA used its discretion in selecting AWPs to include in the array. However, because the various DMERCS had discretion to determine which products to include in a particular array, it is necessary to view arrays for all DMERCs together as well as the guidance given to the DMERCs in order to determine whether products were properly included in arrays. (*See, e.g.*, Reid Decl., Ex. 405 (8/28/09 Bradford Decl.) ¶¶ 11-12). Dey further states that CIGNA used its discretion in selecting AWPs to include in the array which impact the median calculation. For 15 overlapping quarters for which an Administar array is available, the Administar array differs from the CIGNA array in 8 quarters. (*See* Reid Decl., Ex. 405 (8/28/09 Bradford Decl.) ¶ 12). In those eight quarters, a 1% change in Dey's AWP would not result in a different median for these eight Administar arrays. (*See* Reid Decl., Ex. 405 (8/28/09 Bradford Decl.) ¶ 12). Dey incorporates by reference its response to US-SOF No. 205. Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration.

220. During the period April 1, 1997, through September 30, 2001, CIGNA processed for payment 1,165,290 claims for reimbursement for HCPCS codes K0518 or J7644. Of these, 910,835 claims were paid based on an allowed unit amount of either $3.52 or $3.34. (Henderson Ex. 63, at ¶ 14.)

Dey's Response: Dey disputes US SOF No. 220 because it is not supported by the evidence cited. If the Government intended to cite to Henderson Ex. 63, at ¶ 15, US-SOF No.

220 is still unsupported because the declaration cited indicates that CIGNA only paid 1,076,790 claims. Dey further states that CIGNA used its discretion in selecting AWPs to include in the array. Dey incorporates by reference its response to US-SOF No. 205.

221. Dr. Duggan calculates damages to the Medicare program with respect to the ipratropium bromide HPCPS codes by replacing Dey's reported AWPs in the DMERCs' pricing arrays with alternative AWPs (calculated as 125 percent of the average net indirect sales price to the retail pharmacy class of trade), and quantifying the difference in the reimbursement. (Reid Decl. Ex. 270B, pp. 97-131.)

Dey's Response: Dey disputes that the calculations set forth in US-SOF No. 221 calculate "damages." Dey does not dispute that the United States' has set forth Dr. Duggan's methodology in US-SOF No. 221, but states that the report is the best evidence of Dr. Duggan's calculations, and further disputes that Dr. Duggan's calculations are in fact damages.

222. In his report, Dr. Duggan illustrates the effects of considering the impacts of the Dey and Roxane AWPs separately versus jointly in the following table, derived from one of the Palmetto arrays:

NDC	Firm	AWP	Alternative Dey AWP	Alternative Dey & Roxane AWP
00403-0229-18	Compumed	3.22	3.22	3.22
49502-0685-03	Dey	3.53	1.64	1.64
49502-0685-33	Dey	3.52	1.66	1.66
49502-0685-60	Dey	3.52	1.64	1.64
00054-8402-11	Roxane	3.52	3.52	1.70
00054-8402-13	Roxane	3.52	3.52	1.73
00054-8402-21	Roxane	3.52	3.52	1.74
MEDIAN	-	3.52	3.22	1.70

The bottom row shows the median of the listed prices. (Reid Decl. Ex. 270B, p. 98.)

Dey's Response: Dey disputes US-SOF No. 222. US-SOF No. 222 improperly considers Dey and Roxane's AWPs together. Dey has moved for summary judgment on this issue and refers the Court to pages 35-37 of Dey's Motion for Summary Judgment and Section IV C of Dey's Reply in Further Support of its Motion for Summary Judgment. Dey states that

Dr. Duggan's report is the best evidence of his calculations, but disputes that Dr. Duggan's calculations are in fact damages. Dey further disputes US-SOF No. 222 because Palmetto incorrectly included Dey's 2.5 ml 30s UD which is listed as "PF" or preservative free in the 1998 Red Book. (Henderson Ex. 97 at p. 7 of 13). Therefore, pursuant to the Medicare Claims Processing Manual, this product should have been excluded from the array. (Reid Decl., Ex. 400).

223. The third column ("AWP") shows the published AWPs as listed in the original array. In the fourth column ("Alternative Dey AWP"), Dr. Duggan replaces Dey's AWPs with alternative AWPs calculated from Dey's sales transaction data, without replacing any other AWPs. In the fifth column ("Alternative Dey & Roxane AWP"), Dr. Duggan replaces both the Dey and Roxane AWPs with alternative AWPs calculated from the Dey and Roxane sales transaction data, respectively. (Reid Decl. Ex. 270B, p. 98.)

Dey's Response: Dey disputes US-SOF No. 223. US-SOF No. 223 improperly considers Dey and Roxane's AWPs together. Dey has moved for summary judgment on this issue and refers the Court to pages 35-37 of Dey's Motion for Summary Judgment and Section IV C of Dey's Reply in Further Support of its Motion for Summary Judgment. Dey states that Dr. Duggan's report is the best evidence of his calculations, but disputes that Dr. Duggan's calculations are in fact damages. Dey further disputes US-SOF No. 223 because Palmetto incorrectly included Dey's 2.5 ml 30s UD which is listed as "PF" or preservative free in the 1998 Red Book. (Henderson Ex. 97 at p. 7 of 13). Therefore, pursuant to the Medicare Claims Processing Manual, this product should have been excluded from the array. (Reid Decl., Ex. 400).

224. In the "Dey-only" scenario (fourth column), the median drops by $0.30, from $3.52 to $3.22. If one were to calculate a "Roxane-only" scenario, in which the Roxane AWPs were replaced with the alternative AWPs calculated by Dr. Duggan, the resulting median would drop by the same amount of $0.30. (Reid Decl. Ex. 270B, p. 98.)

Dey's Response: Dey disputes US-SOF No. 224. US-SOF No. 224 improperly considers Dey and Roxane's AWPs together. Dey has moved for summary judgment on this issue and refers the Court to pages 35-37 of Dey's Motion for Summary Judgment and Section IV C of Dey's Reply in Further Support of its Motion for Summary Judgment. Dey states that Dr. Duggan's report is the best evidence of his calculations, but disputes that Dr. Duggan's calculations are in fact damages. Dey further disputes US-SOF No. 224 because Palmetto incorrectly included Dey's 2.5 ml 30s UD which is listed as "PF" or preservative free in the 1998 Red Book. (Henderson Ex. 97 at p. 7 of 13). Therefore, pursuant to the Medicare Claims Processing Manual, this product should have been excluded from the array. (Reid Decl., Ex. 400).

225. In the Dey-only and Roxane-only scenarios, the total loss in the above illustration would be $0.60 ($0.30 + $0.30). In the "Dey and Roxane" scenario illustrated above (fifth column), the median drops by $1.82, from $3.52 to $1.70.

Dey's Response: Dey disputes US-SOF No. 225 as it improperly considers Dey and Roxane's AWPs together. Dey has moved for summary judgment on this issue and refers the Court to pages 35-37 of Dey's Motion for Summary Judgment and Section IV C of Dey's Reply in Further Support of its Motion for Summary Judgment. Dey states that Dr. Duggan's report is the best evidence of his calculations, but disputes that Dr. Duggan's calculations are in fact damages. Dey further disputes US-SOF No. 225 because Palmetto incorrectly included Dey's 2.5 ml 30s UD which is listed as "PF" or preservative free in the 1998 Red Book. (Henderson Ex. 97 at p. 7 of 13). Therefore, pursuant to the Medicare Claims Processing Manual, this product should have been excluded from the array. (Reid Decl., Ex. 400).

226. The sum of the calculated losses in the "Dey-only" and "Roxane-only" scenarios is less than the loss calculated in the "Dey and Roxane" scenario. A similar result is described in the Declaration of CIGNA employee Carolyn Helton ¶¶ 32-40. (Henderson Common Ex. 3, ¶¶ 32-40.)

Dey's Response: Dey disputes US-SOF No. 226. US-SOF No. 226 improperly considers Dey and Roxane's AWPs together. Dey has moved for summary judgment on this issue and refers the Court to pages 35-37 of Dey's Motion for Summary Judgment and Section IV C of Dey's Reply in Further Support of its Motion for Summary Judgment. Dey states that Dr. Duggan's report is the best evidence of his calculations, but disputes that Dr. Duggan's calculations are in fact damages. Dey further disputes US-SOF No. 226 because Palmetto incorrectly included Dey's 2.5 ml 30s UD which is listed as "PF" or preservative free in the 1998 Red Book. (Henderson Ex. 97 at p. 7 of 13). Therefore, pursuant to the Medicare Claims Processing Manual, this product should have been excluded from the array. (Reid Decl., Ex. 400).

Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration. Dey objects to the second sentence of US-SOF No. 226 as inadmissible pursuant to Federal Rules of Evidence 602 and 701.

227. Dr. Duggan calculates damages to the Medicare program for ipratropium bromide under three scenarios:

- First, Dr. Duggan calculates damages by replacing the AWPs for Dey's ipratropium bromide products (NDC Nos. 49502-0685-03, 49502-0685-33, 49502-0685-60). In numerous arrays, the median generic AWP does not change, resulting in no calculated damages for those quarters. (Reid Decl. Ex. 270B, pp. 97-101.)

- Second, Dr. Duggan calculates damages by replacing AWPs for Dey's ipratropium bromide products and the AWPs for Roxane's ipratropium bromide generic products, including Roxane's NovaPlus ipratropium bromide products. In this scenario, the allowed amount in every array changes as a result of replacing the AWPs. During the periods when the NovaPlus products are in the brand portion of the arrays, the NovaPlus products are less than the median of the products in the generic portion of the array, and Dr. Duggan attributes all of the losses in those quarters to Roxane. In the quarters when the NovaPlus products

are not in the brand portion of the array, Dr. Duggan allocates the damages between Dey and Roxane according to their relative market shares. (*Id.*, at 101-102 & Table 36; Henderson Ex. 96 (February 2009 supplement to Dr. Duggan's report).)

- Third, Dr. Duggan calculates damages by replacing AWPs for Dey's ipratropium bromide products and the AWPs for Roxane's ipratropium bromide generic products, but not the AWPs for the NovaPlus products. In this scenario, the allowed amount changes in every array. Dr. Duggan allocates the total damages between Dey and Roxane according to their relative market shares. (*Id.*, 101-102 & Table 36; Henderson Ex. 96 (February 2009 supplement to Dr. Duggan's report).)

Dey's Response: Dey disputes US-SOF No. 227. Dey disputes that the figures calculated by Dr. Duggan can be categorized as "damages." Dey states that Dr. Duggan's report is the best evidence of its contents, and Dey disputes the Government's characterization of his report.

Dey further disputes US-SOF No. 227 because it improperly considers Dey and Roxane's AWPs together. Dey has moved for summary judgment on this issue and refers the Court to pages 35-37 of Dey's Motion for Summary Judgment and Section IV C of Dey's Reply in Further Support of its Motion for Summary Judgment. Dey states that Dr. Duggan's report is the best evidence of his calculations, but disputes that Dr. Duggan's calculations are in fact damages.

Dey disputes Dr. Duggan's calculations of market share, because Dr. Duggan does not use Medicare market share to calculate his alleged Medicare damages. Rather, he uses the combined number of Medicaid prescriptions, which are irrelevant and immaterial to Medicare market share. (Henderson Ex. 96).

228. With regard to the second and third alternatives above, because the Medicare allowed amount often was based on the median of the generic AWPs, the submission of inflated AWPs by multiple manufacturers combined to create a joint impact on the Medicare allowed amount that was greater than the sum of the individual impacts. (Reid Decl. Ex. 270B, pp. 14, 124-25; Henderson Ex. 3, ¶¶ 32-40).

Dey's Response: Dey disputes US-SOF No. 228. US-SOF No. 228 improperly considers Dey and Roxane's AWPs together. Dey has moved for summary judgment on this issue and refers the Court to pages 35-37 of Dey's Motion for Summary Judgment and Section IV C of Dey's Reply in Further Support of its Motion for Summary Judgment. Dey states that Dr. Duggan's report is the best evidence of his calculations, but disputes that Dr. Duggan's calculations are in fact damages.

Dey objects to the Government's reliance on Carolyn Helton's Declaration, which was submitted after the close of discovery, contradicts pre-existing facts in the record, and because Dey has not yet had the opportunity to conduct discovery with respect to Ms. Helton's Declaration. Dey objects to the reference to Henderson Ex. 3 as inadmissible pursuant to Federal Rules of Evidence 602 and 701.

229. Palmetto GBA, the DMERC for Region C, was unable to locate pricing arrays for K0518 (ipratropium bromide) for 1999 Q1 and 1999Q2. The Palmetto arrays on either side of this gap, i.e., for 1998 Q4 and 1999 Q3, are reproduced in Henderson Ex. 97. (*See* also Henderson Ex. 98, ¶ 5 & Ex. A.) The 1998 Q4 and 1999 Q3 arrays show the following generic products listed:

Array for 1998 Q4			Array for 1999 Q3	
Compumed	0043-0229-18		Dey	49502-0685-03
Dey	49502-0685-03		Dey	49502-0685-33
Dey	49502-0685-33		Dey	49502-0685-60
Dey	49502-0685-60		Phys Total Care	54868-4082-01
Roxane	00054-8402-11		Phys Total Care	54868-4082-00
Roxane	00054-8402-13		Roxane	00054-8402-11
Roxane	00054-8402-21		Roxane	00054-8402-13
			Roxane	00054-8402-21

Dey's Response: Dey does not dispute US-SOF No. 229, but notes that the generic products listed in the 1998 Q4 and 1999 Q3 Palmetto arrays were chosen by Palmetto for inclusion in those arrays. Furthermore, Dey states that Palmetto incorrectly included Dey's 2.5 ml 30s UD which is listed as "PF" or preservative free in the 1998 Red Book. (Henderson Ex. 97 at p. 7 of 13). Therefore, pursuant to the Medicare Claims Processing Manual, this product should have been excluded from the array. (Reid Decl., Ex. 400). Palmetto's arrays for this period differ from CIGNA's. (*See* Henderson Ex. 97, Henderson Common Ex. 3, Ex. A attached thereto). Furthermore, CIGNA used its discretion in selecting AWPs to include in the array. Dey incorporates by reference its response to US-SOF No. 205.

230. The Palmetto array for 1999 Q3 states, "Deleted Compumed (00403-0229-18) because it was not on Mar 99 CD." (Henderson Ex. 97.)

Dey's Response: Dey does not dispute US-SOF 230.

231. The Red Book annual publications typically are published during the second quarter of each year. (Henderson Ex. 99, at 193:17-193:22.) The Red Book annual publications for 1998 and 1999, show no change in the number or identity of the generic manufacturers of ipratropium bromide from one edition to the next. (Henderson Ex. 97.)

Dey's Response: REDACTED

232. The CIGNA arrays for 1998 Q4, 1999 Ql, and 1999 Q2 show no changes in the manufacturers whose products appear in the arrays during those quarters. (*Id.*; Henderson Ex. 3, Ex. A thereto (AWQ021-0220, AWQ021-0221, AWQ020 CD#1\J7644.xls Tab 1999 Q2).)

Dey's Response: Dey disputes US-SOF No. 232. There is a change in manufacturers in the arrays cited by the Government. Document AWQ020 CD#1\J7644.xls Tab 1999 Q2 includes brand products manufactured by Boehr Ingelheim and Compumed, while AWQ021-0220, AWQ021-0221 do not. Dey disputes US-SOF No. 232 because products do not "appear" in the CIGNA arrays, rather, they were selected by CIGNA employees for inclusion in the arrays.

(Henderson Common Ex. 3, ¶¶ 10-11). Dey and Roxane did not include their products in the arrays.

233. Dey's share of the market for Medicaid-reimbursed ipratropium bromide was approximately 37.5% for the first quarter of 1998. Dey's market share then increased every quarter through the second quarter of 2000, when it peaked at 70.2%. Dey's market share then leveled off to approximately 50% for each subsequent quarter through 2003. From 1998 through 2003, Dey's market share of Medicaid-reimbursed Ipratropium bromide averaged 55.6%. (Henderson Ex. 100.)

Dey's Response: Dey disputes US-SOF No. 233 as immaterial and not supported by the evidence cited. It is not possible to determine the source of the information cited by the United States for purposes of this motion. Dey reserves right to counter these calculations at a later time.

234. Over the Relevant Period, Dey has earned millions of dollars on the Subject Drugs. Examples of evidence of Dey's earnings (consisting of net sales minus costs, expressed as "contribution margin") on the Subject Drugs are as follows: In 1994, Dey earned contribution margins of $65,324,206 for Albuterol Sulfate (NDCs 49502-0697-03, -33, and -60), and $12,128,586 for Cromolyn Sodium (NDCs 49502-0689-02 and -12). (Henderson Ex. 101.) In 1997, Dey earned contribution margins of $1,057,718 for Albuterol MDI (NDC 49502-0196-20); $3,552,833 for Albuterol Inhalation 17gm (NDCs, 49502-0303-17 and -27); $62,630,048 for Albuterol Sulfate (NDCs 49502-0697-03, -33 and -60); $47,778,085 for Ipratropium Bromide (NDCs 49502-0685-03, -33, and -60); and $24,431,859 for Cromolyn Sodium (NDCs 49502-0689-02 and -12). (*Id.*) In 2000, Dey earned contribution margins of $2,077,173 on Albuterol MDI (NDCs 49502-0105-01 and 49502-0196-20 (which was net of a loss on 0196-20 of $45,721)); $2,663,890 on Albuterol Inhalation 17gm (NDCs 49502-0303-17 & -27 and 49502-0333-17 and -27 (net of a loss of $10. For 0333-17); $37,011,793 on Albuterol Sulfate (NDCs 49502-0697-03, -33 and -60); $72,462,937 on Ipratropium Bromide (NDCs 49502-0685-03, -33 and -60); and $6,281,455 on Cromolyn Sodium (NDCs 49502-0689-02 and -12). (*Id.*)

Dey's Response: Dey disputes US-SOF No. 234 as unsupported by the evidence cited. Dey disputes the calculations set forth in Exhibit 101 to the extent they conflict with Dey's own calculations of its contribution margins as set forth in monthly sales reports and other reports generated by Dey's finance department. (*See* Reid Decl., Ex. 312; Ex. 313; Ex. 314; Ex. 315; Ex. 316; Ex. 317; Ex. 318; Ex. 319).

Dated: August 28, 2009

Respectfully Submitted,

KELLEY DRYE & WARREN LLP

By: /s/Sarah L. Reid

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on August 28, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid